HIPAA JOURNAL

HIPAA Compliance Guide

How to make your organization compliant with the Health Insurance Portability and Accountability Act Privacy, Security and Breach Notification Rules

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Contents

1. Introduction

- Introduction to our HIPAA Compliance Guide. What is HIPAAJournal?

2. The Background and Objectives of HIPAA

- A brief history of HIPAA including the points at which complimentary legislation was introduced

3. The HIPAA Privacy Rule

- What is the Privacy Rule? What is PHI? What circumstances does the Privacy Rule cover?

4. The HIPAA Security Rule

- The administrative, physical and technical safeguards that make up the HIPAA Security Rule

5. The HIPAA Notification Rule - What to do in the Event of a Breach

- The procedures you need to follow if patient healthcare information is compromised

6. The HIPAA Enforcement Rule - How is HIPAA-Compliance Enforced?

- Understanding HIPAA audits, enforcement, penalties and Business Associate obligations

7. Secure Communications and HIPAA Compliance

- The highest risk of a breach comes from accidental disclosure. This section details how you can reduce risks and achieve HIPAA compliance

8. The Benefit of HIPAA Compliance Tools

- When HIPAA compliance tools are implemented they bring a number of important benefits!

9. Appendix

- Useful information and references

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1. Introduction

This HIPAA Compliance Guide has been compiled for the benefit of hospital administrators and practice managers who are aware that they have to become HIPAA compliant, but are unsure of what is involved and need to develop a better understanding of HIPAA rules and regulations.

Understanding HIPAA is not easy. Current legislation is comprised of the original 1996 Healthcare Insurance Portability and Accountability Act with additional sections added via the Privacy Rule of 2000, the Security Rule of 2003, The Enforcement Act of 2006, the Health Information Technology for Economic and Clinical Health Act (HITECH) and the American Recovery and Reinvestment Act introduced in 2009 (ARRA).

The Omnibus Final Rule of 2013 enacted further legislation within HIPAA and more changes to the guidelines for protecting patient healthcare and payment information are anticipated in the future as the Meaningful Use incentive program progresses and HIPAA audits are conducted by the US Department of Health and Human Services´ Office for Civil Rights (OCR).

HIPAA legislation is so far-reaching, and covers so many different scenarios, that our intention for this HIPAA Compliance Guide is to provide an extensive outline of what hospital administrators and practice managers need to know before implementing measures to comply with HIPAA.

To recreate multiple HIPAA-related scenarios - and illustrate how HIPAA applies in each - would be confusing and counter-productive. Consequently, we have broken down this HIPAA Compliance Guide into seven separate sections for ease of navigation, and this should serve as the foundation for more focused research, depending on the business nature of the organization or practice.

About HIPAAJournal

HIPAAJournal.com was created to document the progress that has been made in the healthcare industry since the introduction of HIPAA and serves as a depository of information relating to the bill to help covered entities achieve compliance.

HIPAAJournal is committed to reporting the latest news on HIPAA matters, such as new legislative changes, data breaches and OCR actions, while also providing information and guidance to hospital administrators, privacy and security officers and other medical professionals about how to abide by HIPAA Privacy, Security and Breach Notification Rules, hence the issuing of this HIPAA Compliance Guide.

2. The Background and Objectives of HIPAA

The Healthcare Insurance Portability and Accountability Act (HIPAA) was signed into law on 21st August 1996 as an Act to “improve the portability and accountability of health insurance coverage” for employees between jobs, and to combat waste, fraud and abuse in health insurance and healthcare delivery. The Act also contained passages to promote the use of medical savings accounts by introducing tax breaks, provide coverage for employees with pre-existing medical conditions and simplify the administration of health insurance.

The procedures for simplifying the administration of health insurance became a vehicle to encourage the healthcare industry to computerize patients´ medical records. This particular part of the Act spawned the Health Information Technology for Economic and Clinical Health Act (HITECH) in 2009, which in turn lead to the introduction of the Meaningful Use incentive program – described by leaders in the healthcare industry as “the most important piece of healthcare legislation to be passed in the last 20 to 30 years”.

The HIPAA Privacy and Security Rules Take Shape

Once HIPAA had been signed into law, the US Department of Health and Human Services set about creating the first HIPAA Privacy and Security Rules. The Privacy Rule had an effective compliance date of April 14, 2003, and defined Protected Health Information (PHI) as “any information held by a covered entity which concerns health status, the provision of healthcare, or payment for healthcare that can be linked to an individual”. The full list of personal identifiers that are considered to be “linked to an individual” - and are classed as Protected Health Information - can be found in our next chapter dedicated to the HIPAA Privacy Rule.

Instructions were issued on how PHI can be disclosed - and under what circumstances it is possible - while restrictions were placed on the use of PHI for marketing, fundraising, or research - which are only permissible if prior authorization has been obtained in writing from the patient. Patients were also given the right to withhold information about treatment from health insurance providers if that treatment was privately funded.

The HIPAA Security Rule came into force two years later on April 21, 2005. Dealing specifically with electronically stored PHI (ePHI), the Security Rule laid down three security safeguards – administrative, physical and technical – to outline compliance with HIPAA. The safeguards had the following goals:

- **Administrative** – to create policies and procedures designed to clearly show how the entity will comply with the act.
- **Physical** – to control physical access to areas of data storage to protect against inappropriate access
- **Technical** – to protect communications containing PHI when transmitted electronically over open networks

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The Introduction of the Enforcement Rule

The failure of many covered entities to fully comply with the HIPAA Privacy and Security Rules resulted in the introduction of the Enforcement Rule in March 2006. The Enforcement Rule gave the Department of Health and Human Services the power to investigate complaints against covered entities for failing to comply with the Privacy Rule, and to fine covered entities for avoidable breaches of ePHI due to not following the safeguards laid down in the Security Rule.

The Department´s Office for Civil Rights was also given the power to bring criminal charges against persistent offenders who fail to introduce corrective measures within 30 days of a breach. Individuals also have the right to pursue civil legal action against the covered entity if their personal healthcare information has been disclosed without their permission or if it results in “serious harm”.

HITECH 2009 and the Breach Notification Rule

The introduction of the Health Information Technology for Economic and Clinical Health Act (HITECH) in 2009 had the major goals of compelling healthcare authorities to use Electronic Health Records (EHRs) and to join the Meaningful Use incentive program. Stage One of Meaningful Use was rolled out the following year, incentivizing healthcare organizations to maintain PHI in electronic format, rather than in paper files and other physical formats.

With the incentive program also came an extension of HIPAA Rules to include Business Associates and third-party suppliers to the healthcare industry. The introduction of the Breach Notification Rule stipulated that all affected individuals must be notified of a breach within 60 days and that all breaches of ePHI affecting more than 500 individuals must be reported to the Department of Health and Human Services’ Office for Civil Rights. Breaches involving fewer than 500 individuals must also be reported, although covered entities are only required to do this annually. The criteria for reporting breaches of ePHI were subsequently extended in the Omnibus Final Rule of March 2013.

The Omnibus Final Rule of 2013

The most recent legislation to affect HIPAA was the Omnibus Final Rule of 2013. The rule barely introduced any new legislation, but filled gaps in existing HIPAA and HITECH regulations – for example, specifying the encryption standards that need to be applied to render ePHI unusable, undecipherable and unreadable in the event of a breach.

Many definitions were amended or added to clear up grey areas – for example the definition of “Workforce” was changed to make it clear that the term includes employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or Business Associate, is under the direct control of the covered entity or Business Associate.

The Privacy and Security Rules were also amended to allow patient health information to be held indefinitely (the previous legislation had stipulated it be held for fifty years) and to apply new penalties – as dictated by HITECH – to covered entities that fell afoul of the HIPAA Enforcement Rule.

Amendments were also included to account for changing work practices brought about by technological advances, with the Final Rule covering the use of mobile devices in particular. A significant number of healthcare professionals are now using their own mobile devices to access and communicate ePHI, and the

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Omnibus Final Rule included new administrative procedures and policies to account for this, and to cover scenarios which could not have been foreseen in 1996. The full text of the Omnibus Final Rule can be found here.

Consequences of the Omnibus Final Rule

What the Omnibus Final Rule achieved more than any other previous legislation was to make covered entities more aware of HIPAA safeguards that they had to implement. Many healthcare organizations – who had been in breach of HIPAA for almost two decades – implemented a number of measures to comply with the regulations, such as using data encryption on portable devices and computer networks, implementing secure messaging solutions for internal communications with care teams and installing more robust firewalls and multi-layered network security measures.

The financial penalties resulting from data breaches along with the colossal costs of issuing breach notifications, providing credit monitoring services, and conducting damage mitigation makes investment in new technology to protect healthcare data not only efficient but cost-effective.

The HIPAA Compliance Audit Program

In 2011, the Office for Civil Rights commenced a series of pilot compliance audits to assess how well healthcare providers were implementing HIPAA Privacy, Security and Breach Notification Rules. The first round of audits was completed in 2012 and highlighted the dire state of healthcare compliance in America.

Audited organizations registered numerous violations of the HIPAA Breach Notification Rule, Privacy Rule and Security Rule, with the latter resulting in the highest number of violations. The OCR issued action plans to help those organizations achieve compliance; however for the second round of audits mandates compliance, ensuring distribution of financial penalties.

The second round of compliance audits will focus most problematic areas of compliance for healthcare providers. The ultimate goal of the OCR is to run a permanent compliance audit program, and it has taken great strides towards this goal in recent months. The OCR recently implemented a new web portal which streamlines the collection of audit documentation, freeing up resources that will allow it to conduct more audits.

The age of lax security standards has now passed and the healthcare industry, like the financial industry before it, must now raise data security standards to ensure confidential data remains private.

Any covered entity which does not implement the required controls now faces financial penalties, sanctions, and potential loss of license. Criminal proceedings can also be initiated for failing to secure PHI.

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3. The HIPAA Privacy Rule

- What is the HIPAA Privacy Rule?
- What is PHI?
- Use and Disclosure of PHI
- Marketing and Fundraising Protocols
- Patient Access to Medical Records
- Notice of Privacy Practices

What is the HIPAA Privacy Rule?

"The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, healthcare clearinghouses, and those healthcare providers that conduct certain healthcare transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records and to request corrections"

Definition provided by the US Department of Health and Human Services

The HIPAA Privacy Rule regulates the use and disclosure of Protected Health Information (PHI) held by "covered entities", "Business Associates" and third-party service providers who may come into contact with patient healthcare data or payment information.

What constitutes "PHI" is broadly regarded to be any part of an individual´s medical records or payment history and, in order to provide a more comprehensive definition of "PHI" for those who have a responsibility to protect it, we have dedicated an entire section to "What is PHI?" below.

For the purposes of this section, a covered entity is an individual or organization that maintains patient healthcare or payment information. This is likely to include healthcare providers, health plans and healthcare clearinghouses; although some exceptions exist to this generalization.

The Privacy Rule requires covered entities to notify individuals about how their PHI will be used. Covered entities must also keep track of disclosures of PHI and document all privacy policies and procedures. They must appoint a privacy officer and a contact person responsible for receiving complaints and training all members of their workforce about the policies and procedures regarding PHI. In particular, they must address when PHI can be disclosed, to whom, and under what specific circumstances.

A covered entity may disclose PHI to facilitate treatment, payment or healthcare operations without a patient's express written authorization. Any other disclosures of PHI require the covered entity to obtain written authorization from the individual before the use of their information. When a covered entity discloses any PHI, it must make a reasonable effort to disclose only the minimum necessary information required to achieve its purpose.

Covered entities may disclose Protected Health Information to law enforcement officials for law enforcement purposes (including court orders, court-ordered warrants and subpoenas), although care must still be taken

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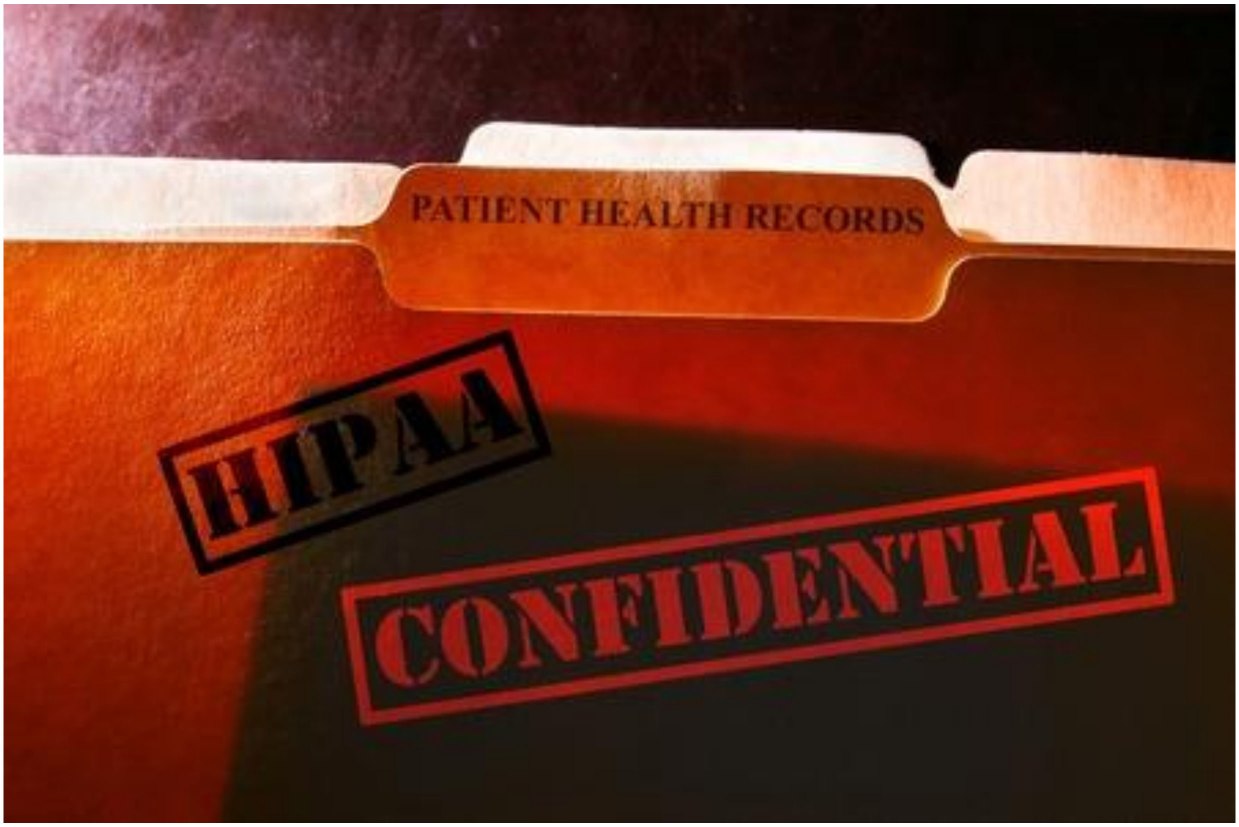
before that information is disclosed. Recently, a medical facility was found to have been negligent for disclosing PHI without first informing the patient (a court ruled that federal law superseded a county-issued subpoena).

In addition to protecting the privacy of individuals, the Privacy Rule aims to make it easier for patients to access their medical information. The Privacy Rule requires covered entities to provide a copy of a patient's healthcare data within 30 days of receiving a written request. They must also disclose PHI, as required by law, in cases of suspected child abuse in order to allow the state child welfare agencies to identify or locate a suspect, fugitive, material witness or missing person.

The Privacy Rule gives individuals the right to request that a covered entity corrects any inaccurate PHI. It also requires covered entities to take reasonable steps to ensure the confidentiality of communications with individuals. An individual who believes that the Privacy Rule is not being upheld can file a complaint with the Department of Health and Human Services' Office for Civil Rights (OCR).

NOTE: The HIPAA Privacy Rule applies to PHI in any form. This includes computer and paper files, x-rays, physician appointment schedules, medical bills, dictated notes, conversations, and information entered into patient portals.



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What is PHI?

As mentioned above, PHI stands for Protected Health Information and is defined as “any information held by a covered entity which concerns health status, the provision of healthcare, or payment for healthcare that can be linked to an individual”. But what is this “information” and who does it apply to?

HIPAA regulations list eighteen different personal identifiers which, when linked together, are classed as Protected Health Information. These eighteen personal identifiers are:

- Names
- All geographical data smaller than a state
- Dates (other than year) directly related to an individual
- Telephone numbers
- Fax numbers
- Email addresses
- Social Security numbers
- Medical record numbers
- Health insurance plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers including license plates
- Device identifiers and serial numbers
- Web URLs
- Internet protocol (IP) addresses
- Biometric identifiers (i.e. retinal scan, fingerprints, Etc.)
- Full face photos and comparable images
- Any unique identifying number, characteristic or code

Who Has a Responsibility to Protect PHI?

Persons with a responsibility to protect PHI and comply with the HIPAA Privacy Rule fall into three main categories - “Covered Entities”, “Business Associates” and “Subcontractors”.

Covered entities are the individuals, institutions or organizations that maintain patient healthcare or payment information or would reasonably be expected to come into contact with PHI in the course of their daily duties - mostly, healthcare providers, health plans and healthcare clearinghouses. Examples of covered entities include:

- **Healthcare Providers -** Healthcare providers include all “providers of services” (e.g., institutional providers such as hospitals) and “providers of medical or health services” (e.g., non-institutional providers such as physicians, dentists and other practitioners) as defined by Medicare, and any other person or organization that furnishes, bills, or receives payment for the provision of healthcare services.

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- **Health Plans -** Individual and group health plans that provide or pay the cost of medical care are covered entities. Health plans include health, dental, vision and prescription drug insurers, health maintenance organizations ("HMOs"), Medicare, Medicaid, Medicare+ Choice and Medicare supplement insurers and long-term care insurers (excluding nursing home fixed-indemnity policies). Health plans also include some employer-sponsored group health plans, government and church-sponsored health plans and multi-employer health plans.

- **Healthcare Clearinghouses -** Healthcare clearinghouses include billing services, repricing companies, community health management information systems and value-added networks that perform clearinghouse functions; such as processing non-standard information they receive from another entity into a standard, or vice versa.

In most instances, healthcare clearinghouses will receive individually identifiable health information only when they are providing these processing services to a health plan or healthcare provider as a Business Associate. In such instances, only certain provisions of the Privacy Rule are applicable to healthcare clearinghouses' uses and disclosures of Protected Health Information.

- **Business Associates** – Business Associates are persons or entities that are not employed by a covered entity, but perform or assist in performing on behalf of a covered entity, a function or activity regulated by HIPAA. A member of a covered entity's workforce is not one of its Business Associates, but a covered entity could in theory be a Business Associate of another covered entity depending on the services it provides.

Business Associate functions or activities on behalf of a covered entity include claims processing, data analysis, utilization review, billing or the provision of data storage or hosting services.

Business Associate services to a covered entity are limited to legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation or financial services.

However, persons or organizations are not considered Business Associates if their functions or services do not involve the use or disclosure of Protected Health Information, and where any access to PHI by such persons would be incidental, if at all.

Business Associates - and independent contractors or subcontractors who are likely to have access to PHI - include, labs and lab technicians, collection agencies, message and confirmation services, IT and technical personnel, non-employed consultants, cleaning crews and staff providing unsupervised after-hours services.

Covered entities engaging in business transactions with Business Associates - who will encounter PHI in the course of the business transaction - must ensure that a "Business Associate Agreement" is in place before any PHI is provided or accessed by the Business Associate. Details of Business Associate Agreements and how they are applied appear in the "How HIPAA is Enforced?" section of this document.

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Use and Disclosure of PHI

The HIPAA Privacy Rule limits how PHI can be used and disclosed to protect patient healthcare and payment information while attempting to avoid the creation of unnecessary barriers impacting delivery of healthcare services.

As such, the HIPAA Privacy Rule generally prohibits a covered entity from using or disclosing PHI unless authorized by patients, except where this prohibition would interfere with delivery of quality healthcare or with certain other important public benefits or national priorities.

Both access to treatment and efficient payment for healthcare services requires the use and disclosure of PHI and is essential to the effective operation of the healthcare system. In addition, certain healthcare operations—such as administrative, financial, legal, and quality improvement activities—conducted by or on behalf of healthcare providers and health plans – are essential for the provision of medical services to patients and for processing payments.

Many individuals expect the use and disclosure of PHI as necessary for providing treatment, and to some extent, to ensure a covered entity's healthcare business can operate efficiently. To avoid interfering with an individual's access to quality healthcare or the efficient payment for healthcare services, the HIPAA Privacy Rule permits a covered entity to use and disclose Protected Health Information, with certain limits and protections, for treatment, payment and healthcare operations activities.

How the Use and Disclosure Criteria Works

The full criteria for what constitutes a "use" or a "disclosure" of PHI are exceptionally long (see HIPAA Privacy Rule §45 CFR 164.501 onwards). In certain circumstances, the disclosure of PHI is allowed without consent; but for the sake of brevity, we have listed the occasions when a covered entity can use or disclose PHI without first obtaining the patient´s consent.

A covered entity may, without the individual's authorization, use or disclose PHI for treatment, payment or the provision of healthcare operations activities under the following scenarios:

- A hospital may use PHI about an individual to provide healthcare to the individual and may consult with other healthcare providers about the individual's treatment
- A healthcare provider may disclose PHI about an individual as part of a claim for payment to a health plan
- A health plan may use PHI to provide customer service to its enrollees

A covered entity may disclose PHI for the treatment activities of any healthcare provider (including providers not covered by the HIPAA Privacy Rule). For example:

- A primary care provider may send a copy of an individual's medical records to a specialist who needs the information to provide treatment
- A hospital may send a patient's healthcare instructions during a patient transfer to a nursing home

A covered entity may disclose PHI to another covered entity or a healthcare provider (including providers not covered by the Privacy Rule) for the payment activities of the entity that receives the information. For example:

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- A physician may send an individual’s health plan coverage information to a laboratory to bill for patient services it provided
- A hospital emergency department may give a patient’s payment information to an ambulance service provider to request payment for transportation services

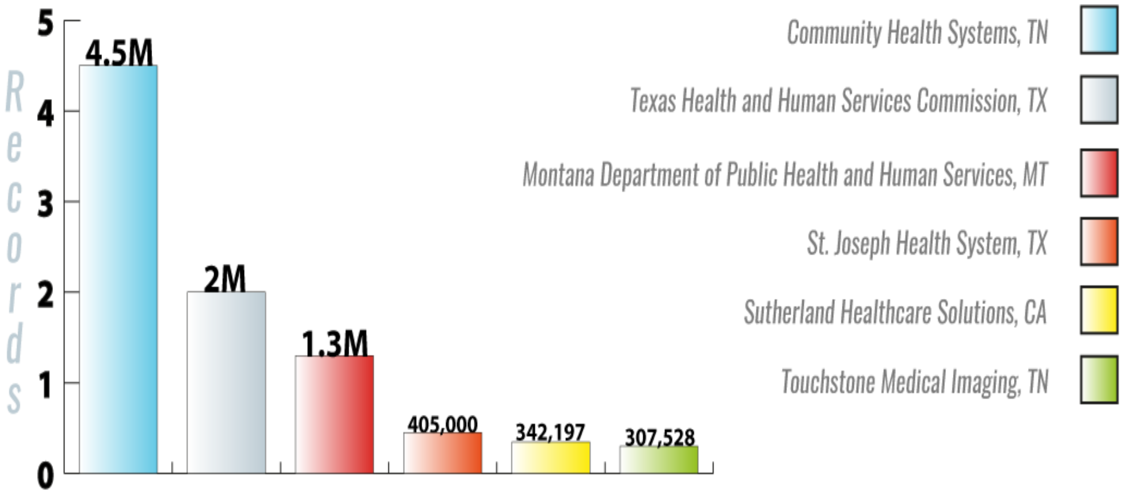
The Minimum Information Necessary

A covered entity must develop policies and procedures that reasonably limit its disclosures of, and requests for, PHI for payment and healthcare operations to the minimum data necessary to achieve the objective.

A covered entity is also required to develop role-based access policies and procedures that limit which members of its workforce may have access to Protected Health Information for treatment, payment and healthcare operations. These policies are discussed further in the Administrative Section of the HIPAA Security Rule.

Covered entities are not required to apply the minimum necessary standard to disclosure requests by a healthcare provider for treatment purposes.

Major 2014 HIPAA Violations



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Marketing and Fundraising Protocols

Restrictions on the use of PHI for Marketing

As you might expect, HIPAA regulations strictly limit what can be done with PHI beyond the standard permitted uses and disclosures. For example, the Privacy Rule expressly prohibits covered entities from selling PHI to third parties for marketing activities without prior patient authorization.

The regulations state that if a covered entity receives “financial remuneration” for communicating treatment or operational information to advertise a third party product or service then prior authorization must be obtained from the individual. With some limited exceptions, Business Associates are prohibited from using PHI for their own purposes.

Refill reminders or other communications about a currently prescribed drug for an individual, including self-administered drugs or biologics (such as insulin pumps) are excluded from this prohibition, but only if any received financial remuneration is reasonably related to the cost of making the communication.

Face to face marketing, including the handing out of written materials such as pamphlets and promotional gifts of nominal value, are also excluded from the authorization requirement so as not to intrude into the doctor-patient relationship and also so that healthcare providers can leave general circulation materials in their offices for patients to pick up during their visits.

Additionally, a communication that is made for the following treatment and healthcare operations purposes, where no financial remuneration is received, are also excluded from this prohibition:

- For the treatment of an individual by a healthcare provider or to direct or recommend alternative treatments, therapies, healthcare providers or settings of care to the individual
- To describe a health-related product or service (or payment for such product or service) that is provided by or is included in a plan - including communications about healthcare provider or health plan networks, enhancements to a health plan, and health-related products or services available only to health plan participants that add value to, but are not part of, an existing plan
- For case management or care coordination, contacting of individuals with information about treatment alternatives and related functions if these activities do not fall within the definition of treatment.

Financial remuneration is defined as "direct or indirect payment from or on behalf of a third party whose product or service is being described" other than payment for treatment of an individual. "Financial remuneration" does not include non-financial benefits, such as in-kind benefits provided in exchange for making a communication about a product or service. If a covered entity is currently sending marketing materials to its participants - or is allowing service providers or vendors to do so through its website - the marketing practices should be reevaluated to comply with the HIPAA Privacy Rule.

Disclosure and Sale of PHI for "Fundraising" Purposes

The Omnibus Final Rule of 2013 further clarified the HITECH Act’s prohibition of the sale of PHI. Under the Omnibus Rule, the sale of PHI generally means a disclosure of PHI if a covered entity receives direct or indirect remuneration from or on behalf of the recipient in exchange for the PHI. It is not necessary for a covered entity to transfer ownership of the PHI for the transaction to constitute a “sale.”

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The Omnibus Final Rule expands the definition of PHI that may be used for fundraising purposes (with patient authorization) to include demographic information relating to the individual - including name, address, other contact information, age, gender and date of birth; dates that healthcare was provided to the individual; information about the general department of treatment (e.g., cardiology, oncology, pediatrics, etc.); the treating physician; outcome information and health insurance status.

If a covered entity uses PHI for authorized fundraising purposes, it must still ensure that only the necessary amount of PHI is used or disclosed. A clear and explicit opt-out must be included with all fundraising communications; however, covered entities are free to decide what methods individuals can use to opt out of future fundraising communications - provided the method does not constitute an undue burden on an individual.

Please note that any use of PHI for marketing or fundraising must be consistent with the covered entities "Notice of Privacy Practices" - a subject that is addressed in our HIPAA Compliance Guide.

Patient Access to Medical Records

The HIPAA Privacy Rule has always provided individuals with the right to access and obtain copies of health information maintained in provider or health plan records. Under the existing regulations, when a patient makes such a request, the covered entity has up to 30 days to provide the requested access or a copy of the requested data; however, the provider or plan can take up to an additional 60 days if the information requested is stored off-site.

Patients can also be charged a reasonable, cost-based fee for copies of their information, to cover the cost of both labor and supplies. This right of access has been part of the Privacy Rule since it was first implemented; although many patients have faced obstacles when trying to obtain timely copies of their health information.

The Privacy Rule covers identifiable health information in both paper and digital form, so this right of patient access has always applied to all forms of PHI. However, in the HITECH Act, Congress made it clear that when a patient's information is stored electronically, patients have the right to obtain an electronic copy and to have that copy sent, at their request, to another person or entity, such as a doctor, caregiver or a personal health record or mobile health app.

New regulations enacted by the Omnibus Final Rule implement this mandate and also clarify how this right to digital data can be exercised. Patients have the right to an electronic copy "in the form or format they request" – but only if the provider or plan is capable of producing the copy in the requested format. If the data isn't "readily producible" in the format requested by the patient, the provider - or plan - and the patient are expected to come to an agreement on an alternative acceptable, machine-readable digital format.

The new rules still allow healthcare providers and health plans to ask patients to submit written requests for copies of their health information, although this is not a requirement of the Privacy Rule. However, if the patient wants to have the electronic copy transmitted directly to a third party, the new rules require that this type of request must be in writing, be signed by the patient and needs to clearly identify the designated recipient and where the information must be sent.

Per existing requirements of the HIPAA Privacy and Security Rules, healthcare providers or health plans sending identifiable health information, per a patient's request, must take steps to verify the identity of the

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patient. They must also conduct checks to ensure the correct records are sent and must implement safeguards to protect the information in transit.

Although the Security Rule requires healthcare providers and health plans to implement safeguards for transmitting identifiable health information, patients also have the right to get their copies through unencrypted channels - such as e-mail - if they so choose. Healthcare providers and health plans are required to advise patients of the risk of receiving information through insecure channels; but if the patient opts for the insecure method, he or she has the right to receive the information in this way.

The requirements for Stage 2 Meaningful Use will provide some patients with more timely, on-line access to relevant digital health information. However, these requirements apply only to entities participating in the Meaningful Use program, and those entities are only required to make this access available to a portion of their patients. HIPAA Rules governing PHI access provide the baseline for all providers using digital records and, for some patients, will constitute the only available pathway for obtaining copies of their data.

Notice of Privacy Practices

Any use or disclosure of Protected Health Information for treatment, payment, or healthcare operations must be consistent with the covered entity's Notice of Privacy Practices (NPPs). A covered entity is required to provide patients or plan members with adequate notice of its privacy practices, including the uses or disclosures of the individual's information together with the individual's rights with respect to that information.

The HIPAA Privacy Rule gave individuals a fundamental new right to be informed of the privacy practices of their health plans and of most of their healthcare providers, as well as to be informed of their privacy rights with respect to their personal health information. Health plans and covered healthcare providers are required to develop and distribute a notice that provides a clear explanation of these rights and practices. The notice is intended to focus individuals' attention on privacy issues and concerns, and prompt them to have discussions with their health plans and healthcare providers.

The HIPAA Privacy Rule states that an individual has a right to adequate notice of how a covered entity may use and disclose Protected Health Information, as well as his or her right to privacy, and the covered entity's obligations with respect to any information that is stored. Most covered entities must develop and provide individuals with this notice of their privacy practices, although the HIPAA Privacy Rule does not require the following covered entities to issue NPPs:

- Healthcare clearinghouses, if the only Protected Health Information they create or receive is in the capacity of a Business Associate of another covered entity. - 45 CFR 164.500(b)(1)
- A correctional institution that is a covered entity (e.g., that has a covered healthcare provider component)
- A group health plan that does not create or receive PHI other than a summary or enrollment/disenrollment information, if benefits are provided through one or more contracts of insurance HMOs/health insurance issuers - 45 CFR 164.520(a).

Other than the above exceptions, covered entities are required to provide a notice in plain language that describes:

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- How the covered entity may use and disclose an individual’s Protected Health Information
- The individual’s rights with respect to the information and how the individual may exercise these rights, including how the individual may lodge a complaint with the covered entity
- The covered entity’s legal duties with respect to the information held, including a statement that the covered entity is required by law to maintain the privacy of Protected Health Information.
- The contact for further information about the covered entity’s privacy policies
- The date this goes into effect

Providing the Notice

A covered entity must make its notice available to any person who asks for it and make it available on any website it maintains, if that site provides information about its customer services or benefits. In this regard, it is important to make a distinction: A website privacy policy is not the same as a Notice of Privacy Practices (NPP).

Health Plans must also:

- Provide the notice to individuals already covered by a health plan and to new enrollees at the time of enrollment
- Provide a revised notice to individuals covered by the plan within 60 days of a material revision
- Notify individuals covered by the plan of the availability of, and how to obtain, the notice at least once every three years

Covered Direct Treatment Providers must also:

Provide the notice to the individual no later than the date of first service delivery and, except in an emergency treatment situation, make a good faith effort to obtain the individual’s written acknowledgment of receipt of the notice. If an acknowledgment cannot be obtained, the provider must document his or her efforts to obtain the acknowledgment and the reason why it was not obtained. In addition, the provider must send an electronic notice automatically and contemporaneously in response to the individual’s first request for service.

In an emergency treatment situation, provide the notice after the emergency situation has ended. In these situations, providers are not required to make a good faith effort to obtain a written acknowledgment from individuals.

Make the latest notice (i.e., the one that reflects any changes in privacy policies) available at the provider’s office or facility (posted for viewing) for individuals to request and take away with them. A covered entity may email the notice to an individual if the individual agrees to receive an electronic notice.

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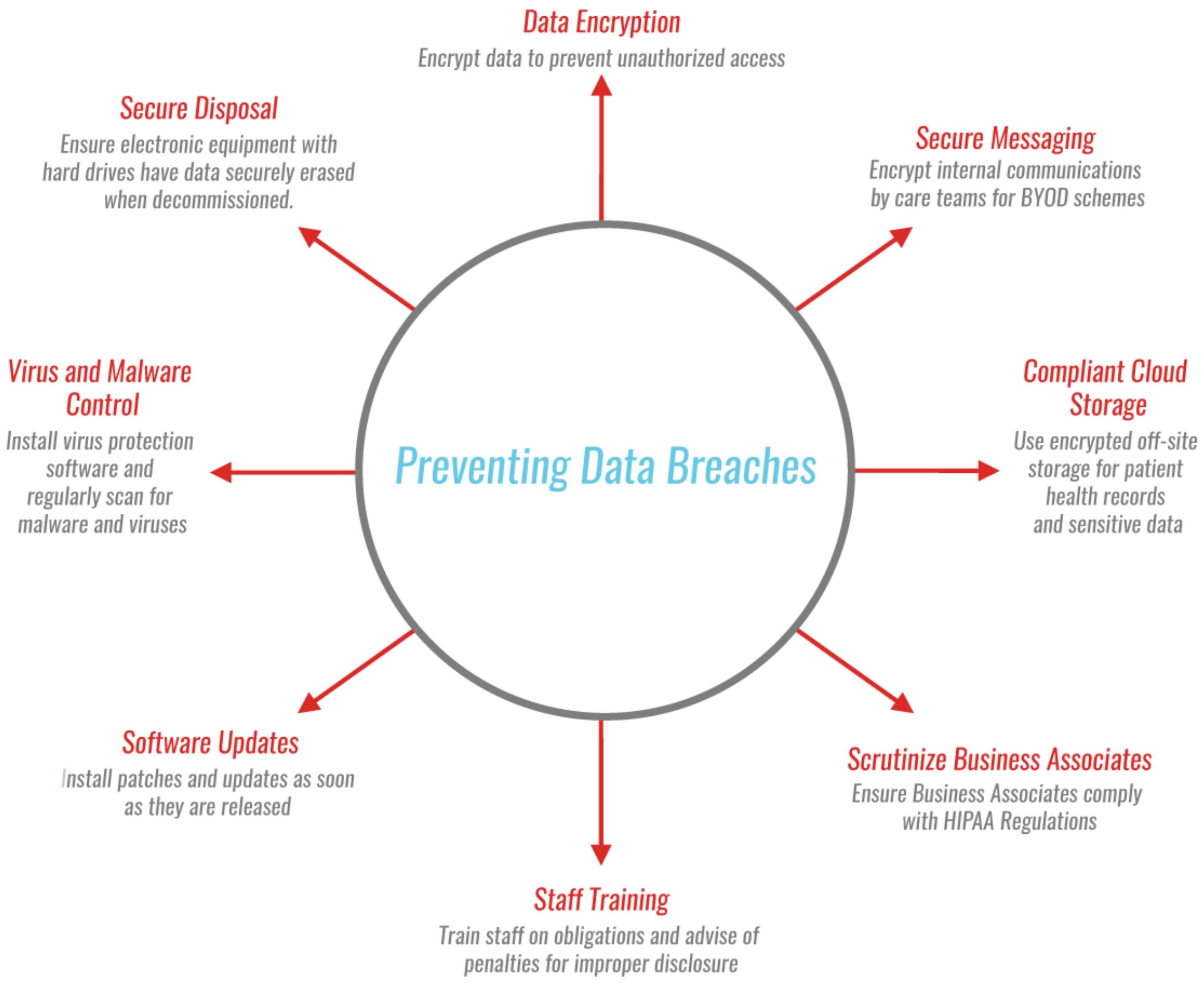
Organizational Options

Any covered entity, including a hybrid entity or an affiliated covered entity, may choose to develop more than one notice, such as when an entity performs different types of covered functions (i.e., the functions that make it a health plan, a healthcare provider or a healthcare clearinghouse) and there are variations in its privacy practices among these covered functions. Covered entities are encouraged to provide individuals with the most specific notice possible.

Covered entities that participate in an organized healthcare arrangement may choose to produce a single but joint notice if certain requirements are met. For example, the joint notice must describe the covered entities and the service delivery sites to which it applies. If any one of the participating covered entities provides the joint notice to an individual, the notice distribution requirement with respect to that individual is met for all of the covered entities.

An example of a Notice of Privacy Practices can be found on the OCR´s website


Data Encryption
Encrypt data to prevent unauthorized access
Secure Messaging
Encrypt internal communications by care teams for BYOD schemes
Compliant Cloud Storage
Use encrypted off-site storage for patient health records and sensitive data
Scrutinize Business Associates
Ensure Business Associates comply with HIPAA Regulations
Staff Training
Train staff on obligations and advise of penalties for improper disclosure
Software Updates
Install patches and updates as soon as they are released
Virus and Malware Control
Install virus protection software and regularly scan for malware and viruses
Secure Disposal
Ensure electronic equipment with hard drives have data securely erased when decommissioned.
Preventing Data Breaches

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4. The HIPAA Security Rule

- What is the HIPAA Security Rule?
- What is the Difference between PHI and ePHI?
- Technical Safeguards
- Physical Safeguards
- Administrative Safeguards
    - Policies, Sanctions and Training
    - Contingency and Disaster Recovery Plans
    - Risk Analysis and Risk Management

What is the HIPAA Security Rule?

"The HIPAA Security Rule establishes national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity. The Security Rule requires appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic Protected Health Information".

Definition provided by the US Department of Health and Human Services

Whereas the HIPAA Privacy Rule deals with the integrity of PHI in general, the HIPAA Security Rule deals with electronic Protected Health Information (ePHI) and is a response to the increasing use of personal mobile devices in the workplace.

The professional use of personal mobile devices in the healthcare industry is significant. More than 80 percent of physicians own at least one mobile device (iPhone, Android phone, Blackberry, iPad, tablets and notebooks etc) with approximately 25 percent utilizing at least two such devices in his or her practice, according to a recent study on the use of mobile devices in the healthcare industry by Gray Reed & McGraw, P.C

The risk of an unauthorized disclosure of ePHI from a personal mobile device is also significant; yet many healthcare organizations have actively pursued "Bring Your Own Device" (BYOD) policies because of the convenience of personal devices, the ease of use and the considerable costs savings in comparison to company devices. This can all too easily lead to unauthorized disclosures of ePHI, in particular in the following scenarios:

- The mobile device is misplaced by the user or is lost or stolen, allowing an unauthorized third party to access ePHI
- The mobile device is left unoccupied or viewable where an unauthorized third party may have access to it
- An unauthorized individual "hacks" into the mobile device's database or accesses ePHI through an insecure channel of communication
- Transferring or placing information on a mobile device (or even a flash drive) that is not encrypted
- The mobile device is traded in without first securely and permanently wiping the data

You may ask yourself “Why would anybody want to access patient healthcare information?” There are in fact many reasons.

Medical records are worth more to hackers than credit cards. With stolen medical records and personal identifiers, hackers can create false IDs to get free medical treatment or acquire drugs that can be resold on the black market. Combined with a false provider number, insurance companies can be billed for treatment that has never taken place or for medical equipment that has never been delivered.

Furthermore, medical identity theft is often not immediately identified by a patient or their provider - giving criminals years to milk stolen medical records. That makes medical data considerably more valuable than credit cards, which tend to be quickly canceled by banks once fraud is detected.

So, whereas the original 1996 Healthcare Insurance Portability and Accountability Act was intended to “combat waste, fraud and abuse in health insurance and healthcare delivery”, one of the main objectives of the HIPAA Security Rule is to protect individuals from becoming victims of fraud and abuse.

What is the Difference between PHI and ePHI?

Whereas “PHI” relates to ALL Protected Health Information irrespective of its format, *electronic* “PHI” (ePHI) is classified as all Protected Health Information that is stored, transmitted or used electronically.

Irrespective of whether ePHI is stored on a desktop computer that only has access to an intranet connection or on a personal mobile device, the HIPAA Security Rule guidelines must be implemented whenever ePHI is in transit or at rest - “at rest” meaning the vehicle on which ePHI has been saved (computer hard drive, flash drive, personal mobile device) and “in transit” relating to any electronic communication (text, IMS, email, pager, file transfer, etc.).

The HIPAA Security Rule also covers how ePHI can be accessed, and by whom, with the administrative, physical and technical safeguards designed to avoid some of the common security gaps that can lead to cyber attacks or an inadvertent loss of data (mobile device theft etc.). The HIPAA Security Rule ensures protection of patients and their ePHI, as well as healthcare facilities and health insurance providers.

In today´s technological environment, it is essential that all covered entities take notice of the Security Rule to ensure full compliance with HIPAA.

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Technical Safeguards

In our “Background and Objectives of HIPAA” we defined the Technical Safeguards of the HIPAA Security Rule as being there to “protect communications containing PHI when they are transmitted electronically over open networks”.

The Security Rule Technical Safeguards concern the technology and related policies and procedures that protect ePHI and control access to it, and they apply to all forms of ePHI. The HIPAA Security Rule requires a covered entity to comply with the Technical Safeguards standards; however it does not go as far as to stipulate the exact methods covered entities must use to protect ePHI.

There is some flexibility as to which security measures are implemented to protect data provided they offer the appropriate degree of protection. That said, a few specific requirements for types of technology to implement are identified in the HIPAA Security Rule.

Together with reasonable and appropriate Administrative and Physical Safeguards, successful implementation of the Technical Safeguards will help ensure that a covered entity protects the confidentiality, integrity and availability of ePHI.

What are the HIPAA Technical Safeguards?

The key areas that hospital administrators and practice managers need to be aware of are:

- **Access Controls** - This means that ePHI can only be accessed by authorized users who have been granted access rights. Mechanisms should be implemented that identify and track user activity, automatically log the user out of the system after a period of inactivity and allow access to ePHI during an emergency.
- **Audit Controls** - These are the overall controls that are put in place to monitor, record and examine all ePHI activity. It is recommended that they are configured in such a way that they complement existing EHR mechanisms and can be used to conduct required risk assessments and to adjust access controls and staff policies as necessary.
- **Integrity** - Maintaining the integrity of ePHI means that it is not destroyed or altered in a way that is non-compliant with HIPAA. Ensuring it is accessed properly and only by authorized users. This not only applies to ePHI in transit, but also at rest - which is covered in the Physical Safeguards.
- **Person or Entity Authentication** - This safeguard is there to ensure that a person who wants access to ePHI is who they say they are. This is usually achieved by passwords or PINs being allocated by an appointed administrator, who has the ability to PIN-lock a device if a risk assessment shows that there is the threat of an ePHI breach or if a device is lost or stolen.
- **Transmission Security** - The security of ePHI during transmission should be established by the use of data encryption. ePHI should be rendered “unreadable, undecipherable or unusable” so that any patient healthcare or payment information is of no use to an unauthorized third party. Effective encryption also helps covered entities avoid a substantial fine should a breach of ePHI occur.

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Physical Safeguards

The Physical Safeguards are a set of rules and guidelines outlined in the HIPAA Security Rule that focus on physical access to ePHI and how the storage of PHI is secure.

There are four standards in the Physical Safeguards:

- Facility Access Controls
- Workstation Use
- Workstation Security
- Devices and Media Controls

Facility Access Controls

Facility Access Controls outline the policies and procedures covered entities must put in place to properly authenticate and authorize access to places where ePHI data is housed. In today's world, this means putting proper procedures in place to ensure that only essential and authorized personnel have access to data centers, server closets, storerooms and any other locations where ePHI is stored. This includes IT storerooms where old computer equipment is held. Many digital devices contain stored ePHI, including digital photocopiers, scanners and printers and access to these devices must also be controlled.

The first implementation specification in the Facility Access Controls standards is called Contingency Operations. In short, covered entities should have a plan in place that ensures that in an emergency, the right people have access to the facilities where ePHI data is physically housed. Effectively, this means putting together a plan so that in an emergency - a data center outage for example - it is possible for PHI data to be accessed or a backup copy of PHI data to be recovered.

It is also important to make sure there is a way to restore the data elsewhere if needed. The data restoration step is typically part of a disaster recovery plan. For example, if the data center housing a HIPAA compliant application loses power, it has to be possible to restore or bring up the application in a second data center (which is why cloud computing is so popular). The rationale for this implementation specification is pretty straightforward. It ensures that even in an emergency situation, access to a patient's PHI is uninterrupted. Just because a computer system is down, doctors still need access to patient records in a timely manner to ensure the provision of healthcare services are not interrupted.

The second implementation specification is called the Facility Security Plan. As the name implies, covered entities need to implement policies and procedures to properly secure and protect the physical facility where ePHI data is housed. Covered entities should establish plans to reasonably and appropriately prevent unauthorized physical access, tampering and theft of ePHI data.

Whether covered entities have an on-site server room or they host their applications in a shared data center, it is their responsibility to ensure that the facility is properly protected. The protection deployed will depend on many factors, such as the size and type of the covered entity, the volume of data stored and the nature of the data which is held. Protection measures could range from making sure a server room is always locked to adding a digital keypad to the section of the building where the server room is located. It may also be appropriate to employ a private security company to patrol the facility. What is important is that there is a plan in place, that it is documented and all appropriate personnel are aware of it. The plan must also be regularly tested and verified.

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The third implementation specification is called Access Control and Validation Procedures. This specification calls for covered entities to put procedures in place to ensure that the people accessing the facility where ePHI is housed are indeed who they say they are, and that their access to PHI is in accordance with his or her role in the organization.

If someone shows up at the location where ePHI is housed claiming to be a computer server technician dispatched to replace a faulty hard drive, then the facility procedures must ensure that access to ePHI data is not inadvertently being provided to an unauthorized person.

The fourth and final implementation specification in the Facility Access Controls standards calls for a covered entity to implement procedures to document any modifications to the facility where ePHI is housed that may affect the facility's security. The procedures put in place should document any additions, changes, removals and repairs to the physical facility housing the ePHI data. Common items logged may include: replacing a broken digital keypad, upgrading the covered entity's video surveillance system, rekeying server room keys and even the reissue of a security badge to authorized personnel.

Workstation Use

The Workstation Use standard states that covered entities must define what each workstation can be used for, how the work on the workstation is performed and the environment surrounding workstations when they are used to access ePHI.

A workstation, in the eyes of the Department of Health and Human Services, is any electronic device that can be used to access ePHI, which includes desktop computers, laptops, mobile devices (including personal mobile phones that have access to ePHI) and tablets. The definition as it is written in the Security Rule is purposely broad to account for all future devices that have not yet come to the market.

Covered entities have to implement policies and procedures to ensure that ePHI access from electronic devices is secure, which includes defining what workstations can be used for. For example, it is possible to be specific and state that workstations can only be used to access an EHR system or that they can only be used by doctors to record patient medical conditions or for doctor-to-patient communications.

It is also common for covered entities to list what cannot be done on a workstation - such as checking personal emails. When policies are defined for this standard, it is possible to be workstation-specific (e.g., by workstation asset ID) or location-specific (e.g., workstations in building 3) or even by workstation type (e.g., every company issued tablet).

Next, the manner in which work is done on the workstations has to be defined. For example, the patient billing system cannot be used with other software, like a web browser, running in the background. Or each user password for the EHR system must be a minimum of six alphanumeric characters in length, contain a combination of upper and lower case characters and cannot include words found in a dictionary.

Finally, the environment surrounding the workstations has to be defined when they are used to access ePHI. Covered entities can again be very specific and restrict ePHI access to only workstations on the third floor, for example.

Parameters can be set around how data is accessed, such as allowing laptops to be used to access ePHI while off company property as long as they are not connected to the internet via Wi-Fi and provided that the connection is through a secure VPN. Indeed, when policies relating to workstation use are being defined,

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keep in mind the staff that works in satellite offices or from home. Policies and procedures have to be in place for them as well. Also do not neglect to consider personal mobile devices brought into the workplace or the use of personal devices at home that can potentially be used to access ePHI.

Workstation Security

Workstation Security is closely related to the Workstation Use standard but there is an important distinction between the two. The Workstation Use standard addresses the policies and procedures for how workstations should be used, whereas the Workstation Security standard addresses how workstations are to be physically protected from unauthorized users.

Every covered entity is different and the Security Rule again calls for reasonable and appropriate measures to be put in place by each entity. In other words, risk assessments should be conducted to determine the level of physical security that is required around each workstation.

Some measures that are easy to implement include ensuring that workstations are positioned in such a way to prevent unauthorized individuals from viewing the screen - by using privacy filters for example - or other measures to make it harder for the devices to be improperly accessed. It may also be appropriate for covered entities to place workstations with access to ePHI in locked rooms.

Only by conducting a full and thorough risk assessment is it possible to determine the risks that exist in a particular facility. The results of that assessment can then be used to develop the appropriate controls based on the covered entity´s physical set-up and requirements.

Device and Media Controls

The fourth and final standard in the Physical Safeguards is Device and Media Controls. This standard calls for covered entities to “implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic Protected Health Information, into and out of a facility, and the movement of these items within the facility.”

The definition is a bit long-winded, but this is because in the eyes of the Department of Health and Human Services, electronic media is any medium that can be used to store or transfer ePHI, and this includes: computer hard drives, removable flash drives, portable USB drives and DVDs. Technically an iPad or any other personal mobile device is also considered electronic media since it can be used to store ePHI either directly, when mapped as a portable hard drive, or indirectly using apps like Box.

The first required implementation specification is titled Disposal. Covered entities must put in place policies and procedures to “address the final disposition of electronic Protected Health Information, and/or the hardware or electronic media on which it is stored.” In other words, when each electronic media device reaches its end of life, covered entities must properly process the electronic media and be absolutely sure all ePHI stored on the digital media has been permanently erased.

Bear in mind that digital devices which are not specifically used to store ePHI may also come into contact with Protected Health Information and maintain a record of that information. This includes digital printers, scanners, photocopiers and fax machines. When files are sent to digital printers, they can be stored on internal memory chips and these will similarly need to be erased before recycling or returning to a leasing company.

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There are several ways to accomplish this. One way is to degauss the electronic media. Degaussing is a process in which a strong magnetic field is applied to magnetic based electronic media such as computer hard drives which permanently erase the stored content. However, the degaussing process does not work on newer storage mediums such as solid state drives and flash drives which are impervious to magnetic fields. Many academic institutions have looked for ways to effectively erase content on non-magnetic drives and have concluded the only sure method is to completely destroy the media. Covered entities need to carefully take inventory of the electronic media currently in use and come up with steps to properly erase content before disposal.

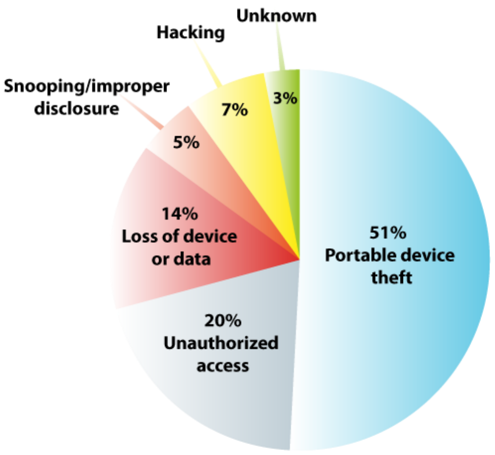
The next required implementation specification is titled Media Re-Use. If covered entities wish to re-use electronic media rather than dispose of them, they are required to put plans in place to ensure all ePHI stored on those devices is permanently destroyed or rendered unreadable before re-use. As pointed out previously, while clearing content on magnetic based storage devices is a fairly easy process, clearing content on non-magnetic storage devices is much more difficult.

For example, deleting files from a desktop computer and emptying the recycle bin is not a sufficient protection as even deleted data can be restored or reconstructed. So once again, a careful review of the electronic media currently used by covered entities should be conducted and procedures developed to ensure that all data is permanently erased.

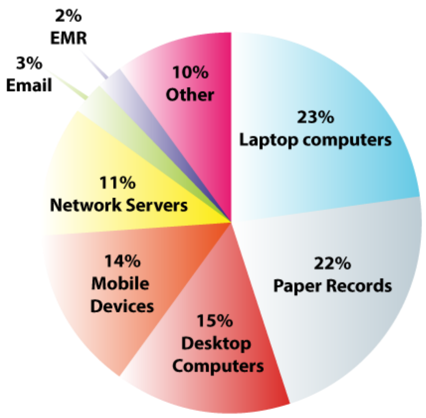
Accountability is the next implementation specification. This implementation specification calls for covered entities to keep records of the movement of hardware and electronic media used to access or store ePHI and to log the person accountable for the move. Covered entities have the flexibility to decide what is considered to be reasonable and appropriate record keeping. Ideally, if a server is removed from the server room for servicing or if a faulty hard drive is replaced for example, covered entities should log the specific device involved and the person who has authorized the change.

The last implementation specification is Data Backup and Storage. Before any hardware and electronic media are physically moved, a backup of the ePHI contained on each media device must be made. This ensures if anything were to happen to the hardware during a move, such as damage, loss or theft, the contained ePHI is protected and data loss is prevented.

Major 2014 HIPAA Violations



Sites of HIPAA Breaches



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Administrative Safeguards

Administrative safeguards are actions, policies and procedures which manage the selection, development, implementation and maintenance of security measures that safeguard electronic Protected Health Information. Administrative safeguards also help HIPAA-covered entities to manage the conduct of their - and their Business Associate's - workforce in relation to the protection of that information.

Administrative safeguards encompass more than half of HIPAA Security requirements. Like the technical and physical safeguards, many of these items are not mandatory but "addressable". This means that all covered entities must give full consideration to each point and assess the relevance of that measure to their own organization. If it is not appropriate to implement a particular (addressable) safeguard - or if it is possible to implement alternative safeguards that offer a similar or greater degree of protection - this is permissible.

Having administrative safeguards in place, in combination with other safeguards, makes it easier for security officers to prevent PHI data breaches and it also allows them to take rapid action when data is compromised or is otherwise exposed.

The Security Rule states that administrative safeguards are, "administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect ePHI and to manage the conduct of the covered entity's workforce in relation to the protection of that information."

This basically calls for those responsible for HIPAA security in healthcare organizations to evaluate preexisting security controls, to accurately and thoroughly analyze risks and to document solutions and translate these into policies and procedures.

The standards for the Administrative Safeguards consist of:

- The Security Management Process
- Assigned Security Responsibility
- Workforce Security
- Information Access Management
- Security Awareness and Training
- Security Incident Procedures
- Contingency Planning
- Evaluation
- Business Associate Contracts and Other Arrangements

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The Security Management Process

The Security Management Process covers the implementation of policies and procedures to prevent, detect, contain and correct security violations.

These are categorized into 4 implementation specifications:

Risk Analysis (Required)

A risk analysis is one of the most important elements of HIPAA Security Rules, yet it is one of the most common areas of non-compliance as highlighted by the pilot audit program. A risk analysis is a procedure by which the entire organization is assessed for potential security vulnerabilities and risks to the confidentiality, integrity and availability of electronic Protected Health Information (ePHI) held by the covered entity.

If a risk analysis is conducted that is not comprehensive - I.e. does not cover all aspects of data security for both physical PHI and ePHI - security vulnerabilities are likely to remain that could place the confidentiality of health records in jeopardy. Only by identifying ALL risks can an organization take action to effectively manage those risks.

A risk analysis is not a onetime action, but a continuous process of reevaluation and assessment that should take place at regular intervals, in particular after a material change in HIPAA legislation or as part of the process of implementing new software or computer systems that have potential to come into contact with PHI.

Risk Management (Required)

Once a risk analysis has been conducted and all potential security vulnerabilities identified, the covered entity must then implement security measures sufficient to reduce those risks and vulnerabilities to a reasonable and appropriate level.

Sanction Policy (Required)

A sanction policy must be put in place to allow the covered entity to take action against workforce members who fail to comply with the security policies and procedures of the covered entity. The staff should be made aware of HIPAA Privacy, Security and Breach Notification Rules and must agree to abide by them. All sanctions that will be applied following a violation of HIPAA procedures, such the termination of an employment contract, must be communicated to the staff.

Information System Activity Review (Required)

It is essential that all covered entities implement a system, preferably automated, which logs all system activity relating to PHI, in particular any requests to access patient records or make amendments to PHI. Audit logs must be created and the system must be capable of generating security incident tracking reports.

Even the most robust security systems cannot prevent authorized users from accessing PHI improperly, so it is essential that all attempts to view or alter PHI are logged, and that these logs are regularly checked for inappropriate access as one of the main causes of HIPAA breaches is employee snooping and data theft by authorized users.

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Assigned Security Responsibility

A security official should be appointed and given the responsibility for the development and implementation of HIPAA policies and procedures relating to data security.

While one person must be given overall responsibility for all security responsibilities, other individuals can be assigned individual responsibilities such as network security, device management or site security, provided they report to the security official with overall responsibility for HIPAA compliance. In large organizations, it may be necessary to assign tasks to numerous individuals, and may be of benefit to appoint separate Privacy and Security officials, especially in larger and more complex organizations.

Workforce Security

Access to PHI must be restricted and carefully controlled, yet healthcare professionals do require access to PHI in order to do their jobs and provide healthcare services to patients. This means that policies and procedures must be developed to ensure that all members of the workforce have appropriate access to ePHI, as provided under the Information Access Management standard, while others must be prevented from viewing ePHI.

Workforce security comprises three implementation specifications:

Authorization and/or Supervision (Addressable)

Policies must be developed and procedures implemented which allow users to be granted authorization to access or amend ePHI commensurate with their position. In practice this means assessing job descriptions to determine what degree of access is required. All members of staff granted with access to ePHI must be supervised in locations where data may be accessed.

Workforce Clearance Procedure (Addressable)

A clearance procedure must exist that assesses whether the level of access to ePHI that an individual workforce member needs to perform his or her duties is appropriate. A clearance procedure must verify that an individual has an appropriate level of access to perform their duties.

Termination Procedures (Addressable)

Just as procedures must be developed to grant users access to essential ePHI, procedures must also be in place to terminate those access rights when they are no longer required, such as following a change in the individual’s duties or after the termination of an employment contract.

Information Access Management

The fourth standard covers the management of access to ePHI by members of the workforce who need to view, amend or update ePHI as part of their daily duties. Controlling access is an essential element of data security that limits the potential for accidental or deliberate disclosure of PHI to non-authorized individuals, while also limiting the possibility of erasure or alteration of ePHI.

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Information Access Management includes three implementation specifications:

Isolating Healthcare Clearinghouse Functions (Required)

If a healthcare clearinghouse is part of a larger organization, the clearinghouse must implement policies and procedures that protect the ePHI of the clearinghouse from unauthorized access by the larger organization.

Access Authorization (Addressable)

This specification is similar to that stated in the Workforce Security section, but instead of determining access rights, Access Authorization requires policies and procedures to be implemented for granting access to ePHI, such as through a particular workstation or for specific transactions, programs, processes or other mechanisms.

Access Establishment and Modification (Addressable)

A covered entity must implement policies and procedures that, based upon the entity's access authorization policies - establish, document, review and modify a user's right of access to a workstation, transaction, program, or process.

Security Awareness and Training

One of the most important elements of the administrative safeguards is the provision of training on HIPAA Security and Privacy Rules, not only for the staff that is granted access to ePHI or may otherwise come into contact with it, but all members of the workforce, including management. Even the most robust security policies can be easily compromised due to poor or non-existent staff training.

Security Awareness and Training includes four implementation specifications:

Security Reminders (Addressable)

The provision of training ensures that the workforce is fully aware of HIPAA Privacy and Security Rules; however policies frequently need to be updated and these changes must be communicated to the staff. It is also important to provide the workforce with reminders of the importance of data security and PHI policies and procedures.

All reminders must be documented and a record maintained, while the procedures must govern the issuing of reminders, such as via electronic bulletins, the posting of security reminders on notice boards and the creation of agendas for periodic staff meetings etc.

Protection from Malicious Software (Addressable)

Covered entities must put procedures into place which guard against, detect and report malicious software, including computer viruses such as Trojans, worms, key loggers and malware. Viruses and malware can be used by external parties to gain access to data or to convince authorized personnel to divulge their login credentials and security keys. It can also damage, delete or otherwise alter data.

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All members of the workforce must receive training to help them identify potentially dangerous software and training also provided to ensure all staff know how, and to whom, to report malicious software. This includes developing policies which restrict how the internet is used and what can be downloaded.

Log-in Monitoring (Addressable)

Procedures must be developed for monitoring log-in attempts and reporting discrepancies. A system must be in place that can log access attempts, such as multiple attempts to gain access to ePHI using incorrect passwords or usernames. Systems can be configured to log these attempts and generate security reports, or even to block access for a particular user or device. One measure which can be employed is the blocking of a login after a set number of access attempts have failed.

Password Management (Addressable)

Procedures must be developed to cover creating, changing and safeguarding passwords used to access ePHI. If passwords are not automatically assigned, training must be provided on creating secure passwords, such as not using dates of birth, children's names or passwords that can easily be guessed (password, 123456 etc.).

Policies should be developed that require users to change their passwords at regular intervals and the staff should be advised about how passwords can be safeguarded.

Security Incident Procedures

Even the most security conscious healthcare organizations that have implemented multi-layer security systems and are fully HIPAA-compliant will, at some point in time, experience a security incident. While it is possible to reduce and manage risk, it is not possible to eliminate it entirely. Covered entities must therefore implement procedures that allow these incidents to be reported quickly, and to the appropriate personnel.

There is only one implementation specification:

Response and Reporting (Required)

This specification states that all HIPAA-covered entities must be able to "identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity; and document security incidents and their outcomes."

There are numerous types of security incident, and the workforce must be aware how to "Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity; and document security incidents and their outcomes."

Examples of security incidents include, but are not limited to:

- Loss or theft of portable devices containing unencrypted ePHI
- Stolen or divulged passwords
- Computer viruses and malware
- Corrupted backup tapes that do not allow ePHI to be restored
- Break-ins resulting in the theft of devices containing ePHI
- The use of old logins - such as those of terminated members of staff - to access ePHI
- The accessing of ePHI by non-authorized members of staff

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Procedures must be developed which allow a rapid and adequate response to each of these threats, and any others that may exist in a particular organization.

Contingency Planning

Access to ePHI must be maintained at all times, even during emergencies. Procedures must therefore be developed to ensure that this is the case. Covered entities must "Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and natural disaster) that damages systems that contain ePHI."

Contingency Planning includes five implementation specifications:

Data Backup Plan (Required)

Entities must establish and implement procedures to create and maintain retrievable exact copies of ePHI. All data, including health information, diagnostic images, medical records, accounting information and other electronic documents must be frequently backed up, and any physical backup tapes, if used, must be stored off-site in a secure location protected by the physical safeguards mentioned above.

Disaster Recovery Plan (Required)

HIPAA-covered organizations must establish (and implement as needed) procedures to restore any loss of data and this plan must be reviewed and revised frequently.

Emergency Mode Operation Plan (Required)

Even during a power outage or other emergency situation such as a server malfunction, procedures must exist to ensure the continuation of critical business processes and the protection of ePHI while operating in emergency mode.

Testing and Revision Procedures (Addressable)

All Contingency Plan implementation specifications must be subjected to tests to ensure that data can be restored, and emergency operational procedures must similarly be subjected to live tests to ensure they are effective. These tests should be conducted on a regular basis and policies and procedures revised as appropriate.

Applications and Data Criticality Analysis (Addressable)

Covered entities are required to "Assess the relative *c*riticality specific applications and data in support of other contingency plan components." This means that all software and computer systems must be evaluated and given priority for backups - and restoration of data from backup tapes and devices - based on their importance to the running of the organization and the provision of patient healthcare services.

Evaluation

This standard covers the monitoring and evaluation of all security measures to ensure that they continue to offer the appropriate level of protection to keep ePHI secure.

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Over time, systems and personnel will change, new technology will be introduced and environmental and operational environments are also subject to change. Naturally, policies and procedures must be updated to take these new occurrences and changes into account.

There are no implementation specifications under this standard. Covered entities are just required to "Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and subsequently, in response to environmental or operations changes affecting the security of ePHI that establishes the extent to which an entity's security policies and procedures meet the requirements of this subpart [the Security Rule]."

Business Associate Agreements and Other Arrangements

The last standard under administrative safeguards covers Business Associates - and their subcontractors - and requires a covered entity to enter into a Business Associate Contract with any third party that creates, receives, maintains or transmits ePHI.

This is a required element, and a covered entity, in accordance with § 164.306 [the Security Standards: General Rules], may permit a business associate to create, receive, maintain, or transmit ePHI on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with § 164.314(a) [the Organizational Requirements] that the business associate will appropriately safeguard the information (Emphasis added)."

There is a single implementation specification for this standard:

Written contracts

Covered entities must "Document the satisfactory assurances required by paragraph (b) (1) [the Business Associate Contracts and Other Arrangements] of this section through a written contract or other arrangement with the business associate that meets the applicable requirements of §164.314(a) [the Organizational Requirements]."

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5. The Breach Notification Rule - What to do in the Event of a Breach

- The HIPAA Breach Notification Rule
- OCR Fines and Civil Action

The HIPAA Breach Notification Rule

Even with all the safeguards in the world, patient healthcare and payment information can be compromised. Risks can be effectively managed, but it is impossible to prevent employees snooping or to prevent human error entirely. As mentioned in our explanation of the Security Rule, mobile devices can be misplaced, left unattended, be stolen or traded in without proper data removal.

If covered entities follow the administrative, technical and physical safeguards of the HIPAA Security Rule - and ePHI is encrypted to a standard that would make it “unusable, indecipherable or unreadable” - it may not be necessary to report data breaches. If the information it contains cannot be accessed, there will be no breach of HIPAA rules.

The definition of a breach provided by the US Department of Health and Human Services is as follows:

“A breach is, generally, an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of the Protected Health Information.” An impermissible use or disclosure of Protected Health Information is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the Protected Health Information has been compromised based on a risk assessment of at least the following factors:

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- The nature and extent of the Protected Health Information involved, including the types of identifiers and the likelihood of re-identification
- The unauthorized person who used the Protected Health Information or to whom the disclosure was made
- Whether the Protected Health Information was actually acquired or viewed
- The extent to which the risk to the Protected Health Information has been mitigated

If, despite all precautions, a breach has occurred which potentially could result in the unauthorized disclosure of a patient´s healthcare and/or payment information, the affected patients and the Secretary of the Department of Health and Human Services must be informed within 60 days of the discovery of the breach.

Informing a Patient of a Breach of ePHI

To inform a patient of a breach of ePHI, a notification must be sent by first class mail to the last known address of the patient, the next of kin if the patient is deceased or the parent or guardian of a child under the age of eighteen whose healthcare information has been compromised.

If the breach requires urgent attention because of a possible imminent misuse of ePHI, the patient should also be contacted by telephone or by any other means of communication that is considered appropriate. The content of the notification should include:

- A brief description of what happened, including the date of the breach and the date of discovery of the breach
- A description of the type(s) of information that was compromised in the breach (personal identifiers such as name, address, Social Security number, account numbers, etc)
- The measures individuals should take to protect themselves from potential harm as a result of the breach
- A brief description of what the covered entity is doing to investigate the breach, to mitigate losses and to prevent a repeat of the breach
- Contact details for individuals to ask questions or request further information, which should include a toll-free number, an email address, website or postal address

Informing the Department of Health and Human Services

Informing the Department of Health and Human Services that a breach of ePHI has occurred is done using the department´s online notification form. The procedures for reporting a breach of ePHI differ depending on the number of patient records that have been compromised (or have potentially been compromised):

Data Breaches Affecting Fewer Than 500 Individuals

If a breach of unsecured Protected Health Information affects fewer than 500 individuals, a covered entity must notify the Secretary of the breach within 60 days of the end of the calendar year in which the breach was discovered.

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This does not mean that a covered entity must wait until the end of the calendar year to report breaches affecting fewer than 500 individuals. As a "Best Practice" it is advisable to report the breach as soon as the details of the breach have been established.

A covered entity may report all of its breaches affecting fewer than 500 individuals on one date, but a separate notice must be issued for each breach incident.

In early 2015, the OCR updated the breach reporting portal and replaced the online form with a Javascript wizard to guide the user through the reporting process. This new system streamlines the collection of data, allows specific questions to be asked and ensures that all information relating to the breach is recorded in sufficient detail. Compliance officers should familiarize themselves with the data that must be entered after a breach, rather than leaving the reporting until the year end when it may be more difficult to obtain the necessary information.

While the Secretary of the department of Health and Human Services is happy to wait to find out about these smaller breaches, the individuals affected by the breach must still be notified within 60 days of the discovery of the breach.

Data Breaches Affecting More Than 500 Individuals

If a breach of unsecured Protected Health Information affects 500 or more individuals, a covered entity must notify the Secretary about the breach without unreasonable delay, and in no case later than 60 calendar days from the discovery of the breach.

If the number of individuals affected by a breach is unknown, the covered entity should provide an estimate, and, if it discovers additional information relating to the breach, it may submit additional information by checking the appropriate box to indicate that an addendum to the initial report has been added, making sure the transaction number of the initial breach report is included to ensure the data can be matched.

Data Breaches Caused by a Business Associate

A Business Associate of a covered entity that accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured Protected Health Information shall, following the discovery of a breach of such information, notify the covered entity. The notice must identify each individual whose unsecured Protected Health Information has been, or is reasonably believed by the Business Associate to have been, accessed, acquired or disclosed as a result of the breach.

For the purposes of clarification, the HIPAA Breach Notification Rule and the HITECH Notification Rule are practically the same. The notification procedures were established by HITECH in 2009, but slight changes to the definition of breaches were made in the Omnibus Final Rule of 2013.

A more significant change introduced with the Omnibus Final Rule of 2013 was to place the burden of proof on the covered entity, which must determine (through a risk assessment) that a breach of ePHI has not occurred. Previously the onus was on the Office for Civil Rights to prove that a HIPAA breach had occurred, whereas now any potential exposure of PHI is considered to be a breach unless the covered entity can prove otherwise.

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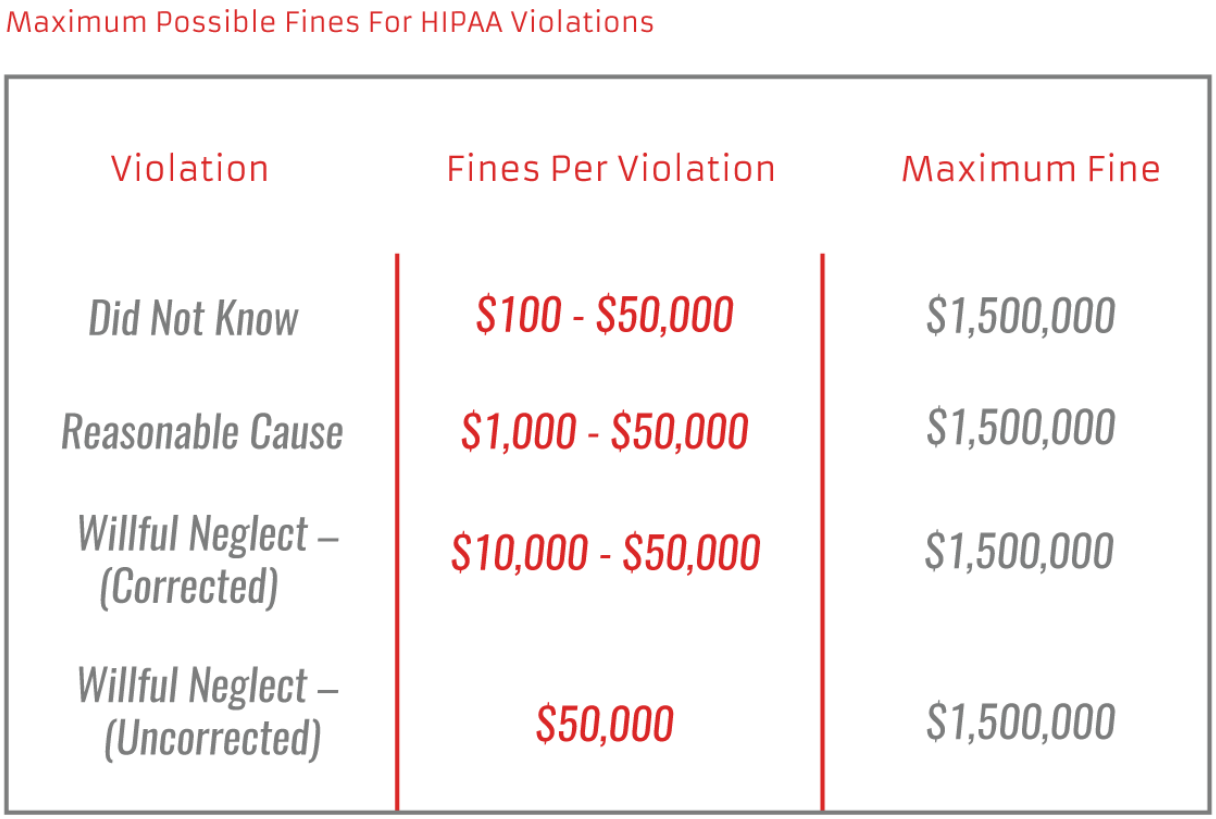
OCR Fines and Civil Action

Later in our HIPAA Compliance Guide we discuss how HIPAA is enforced and what happens after the Department of Health and Human Services has been notified of a breach; however, this is a suitable point to discuss the fines that can be issued by the Office for Civil Rights, and other penalties that can be applied following a breach of ePHI.

The HIPAA Enforcement Rule is the area of legislation that governs the investigations that follow a breach of ePHI, the penalties that can be imposed on covered entities responsible for an avoidable breach of ePHI and the procedures for hearings.

Covered entities should be aware that there is a significant difference in the financial penalties that can be issued, and that they depend on the efforts that have been made to protect the integrity of patient´s healthcare and payment information prior to the breach, and also the actions taken after the breach to mitigate any damage caused.

HIPAA Breach Financial Penalty Structure

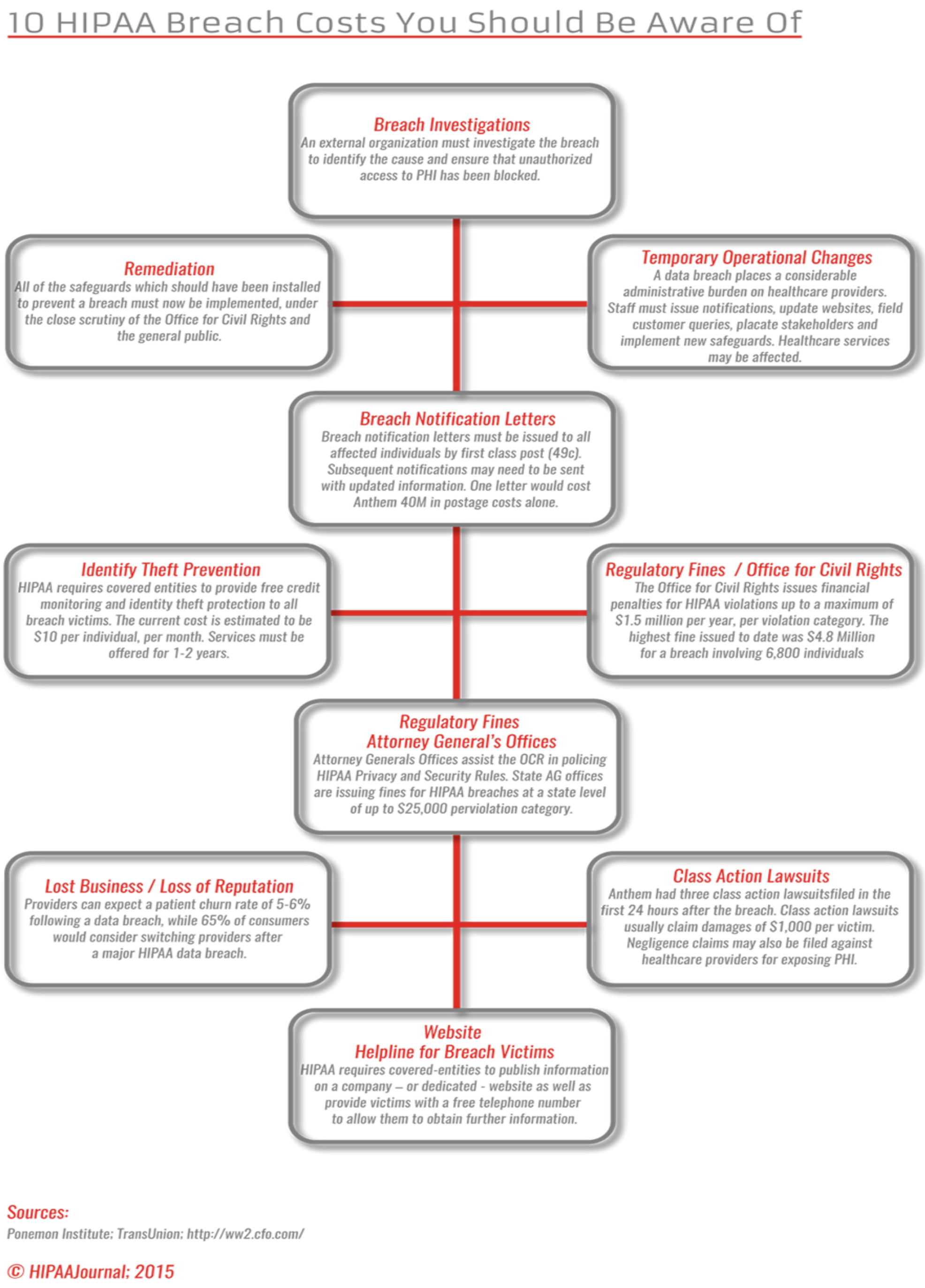


Maximum Possible Fines For HIPAA Violations

Violation	Fines Per Violation	Maximum Fine
Did Not Know	$100 - $50,000	$1,500,000
Reasonable Cause	$1,000 - $50,000	$1,500,000
Willful Neglect – (Corrected)	$10,000 - $50,000	$1,500,000
Willful Neglect – (Uncorrected)	$50,000	$1,500,000

Fines are imposed per violation category and reflect the number of records exposed in a breach and the risk to individuals from the exposure of their data. Penalties can easily reach the maximum fine of $1,500,000 per violation category, per calendar year. It should also be noted that the penalties for willful neglect can also lead to criminal charges being filed, while civil lawsuits for damages can be filed by victims of a breach regardless of the category.

As a point of interest, historic civil cases have shown covered entities to be treated more leniently when they have made an effort to comply with HIPAA. When safeguards have been introduced to protect the integrity of ePHI, but a breach has happened regardless, courts will only entertain claims for civil damages if an injury has been sustained - or damage suffered - by the patient whose healthcare or payment information has been compromised.



10 HIPAA Breach Costs You Should Be Aware Of

Breach Investigations
An external organization must investigate the breach to identify the cause and ensure that unauthorized access to PHI has been blocked.

Remediation
All of the safeguards which should have been installed to prevent a breach must now be implemented, under the close scrutiny of the Office for Civil Rights and the general public.

Temporary Operational Changes
A data breach places a considerable administrative burden on healthcare providers. Staff must issue notifications, update websites, field customer queries, placate stakeholders and implement new safeguards. Healthcare services may be affected.

Breach Notification Letters
Breach notification letters must be issued to all affected individuals by first class post (49c). Subsequent notifications may need to be sent with updated information. One letter would cost Anthem 40M in postage costs alone.

Identify Theft Prevention
HIPAA requires covered entities to provide free credit monitoring and identity theft protection to all breach victims. The current cost is estimated to be $10 per individual, per month. Services must be offered for 1-2 years.

Regulatory Fines / Office for Civil Rights
The Office for Civil Rights issues financial penalties for HIPAA violations up to a maximum of $1.5 million per year, per violation category. The highest fine issued to date was $4.8 Million for a breach involving 6,800 individuals

Regulatory Fines
Attorney General's Offices
Attorney Generals Offices assist the OCR in policing HIPAA Privacy and Security Rules. State AG offices are issuing fines for HIPAA breaches at a state level of up to $25,000 perviolation category.

Lost Business / Loss of Reputation
Providers can expect a patient churn rate of 5-6% following a data breach, while 65% of consumers would consider switching providers after a major HIPAA data breach.

Class Action Lawsuits
Anthem had three class action lawsuitsfiled in the first 24 hours after the breach. Class action lawsuits usually claim damages of $1,000 per victim. Negligence claims may also be filed against healthcare providers for exposing PHI.

Website
Helpline for Breach Victims
HIPAA requires covered-entities to publish information on a company – or dedicated - website as well as provide victims with a free telephone number to allow them to obtain further information.

Sources:
Ponemon Institute; TransUnion; http://ww2.cfo.com/

© HIPAAJournal: 2015

6. The HIPAA Enforcement Rule - How is HIPAA Compliance Enforced?

How the OCR Regulates HIPAA Privacy, Security & Breach Notification Rules

OCR is responsible for enforcing HIPAA Privacy and Security Rules (45 C.F.R. Parts 160 and 164, Subparts A, C, and E). One of the ways that the OCR carries out this responsibility is to investigate complaints that have been filed. The OCR may also conduct compliance reviews to determine if covered entities have implemented the appropriate policies and procedures demanded by HIPAA.

The OCR also issues guidance and performs education and outreach programs to foster compliance with all requirements of the Privacy and Security Rules.

However, the OCR may only take action on certain types of complaints. See what the OCR considers during intake and review of a complaint for a description of the types of cases in which it cannot act or take enforcement actions.

If the OCR accepts a complaint for investigation, it will notify the person who filed the complaint and the covered entity named in it. The complainant and the covered entity are then asked to present information about the incident or the problem described in the complaint. The OCR may request specific information from each party to gain an understanding of the facts of each case. Covered entities are required by law to cooperate fully with all complaint investigations.

If a complaint describes an action that could be a violation of the criminal provision of HIPAA (42 U.S.C. 1320d-6), the OCR may refer the complaint to the Department of Justice for further investigation.

The OCR reviews all information, or evidence, that it gathers in each case. In some cases, it may determine that the covered entity did not violate the requirements of the Privacy or Security Rule. If the evidence indicates that the covered entity was not in compliance, the OCR will attempt to resolve the case with the covered entity by obtaining:

- Voluntary compliance;
- Corrective action; and/or
- A resolution agreement.

Most Privacy and Security Rule investigations are concluded to the satisfaction of the OCR through these types of resolutions. The OCR notifies the person who filed the complaint and covered entity of the resolution result in writing.

If the covered entity does not take action to resolve the matter in a way that is deemed to be satisfactory, the OCR may decide to impose civil money penalties (CMPs) on the covered entity. If CMPs are imposed, the covered entity may request a hearing in which an HHS administrative law judge decides if the penalties are appropriate and are supported by evidence. Complainants do not receive a portion of CMPs collected from covered entities; instead the penalties are deposited in the U.S. Treasury.

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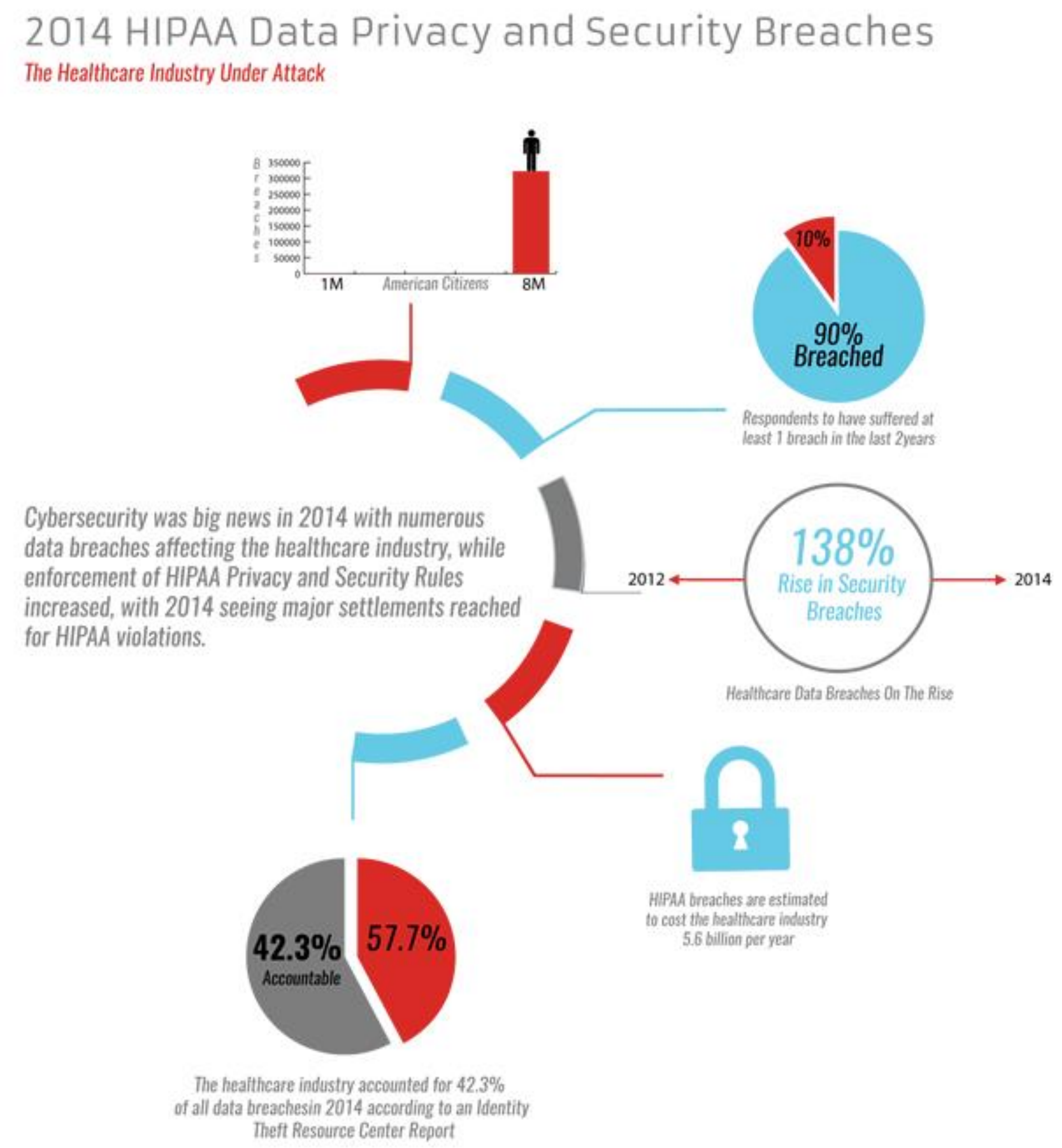

2014 HIPAA Data Privacy and Security Breaches

The Healthcare Industry Under Attack

Respondents to have suffered at least 1 breach in the last 2years

Cybersecurity was big news in 2014 with numerous data breaches affecting the healthcare industry, while enforcement of HIPAA Privacy and Security Rules increased, with 2014 seeing major settlements reached for HIPAA violations.

Healthcare Data Breaches On The Rise

HIPAA breaches are estimated to cost the healthcare industry 5.6 billion per year

The healthcare industry accounted for 42.3% of all data breachesin 2014 according to an Identity Theft Resource Center Report

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Background to the OCR Privacy, Security and Breach Notification Pilot Audit Program

The use of health information technology continues to expand in healthcare. New technologies provide many benefits for consumers, but they also introduce new risks to consumer privacy.

The Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) set national minimum standards to protect PHI and to effectively manage those risks, such as securing electronic Protected Health Information and issuing breach notification to individuals affected by a data breach to allow them to take action to protect themselves against identity theft and medical fraud.

HITECH also places a requirement on the HHS - via its Office for Civil Rights - to perform periodic audits of covered entities - including Business Associates - to assess for compliance with HIPAA Privacy, Security and Breach Notification Rules.

In 2011, the OCR developed a program of pilot audits to assess the general state of compliance with HIPAA in the healthcare industry, which included an assessment of the controls and processes covered entities have put in place to comply with HIPAA Rules.

The OCR developed a protocol, or set of instructions, which it then used to measure the efforts of 115 covered entities. As part of the OCR’s continued commitment to protect health information, the office instituted a formal evaluation of the effectiveness of its pilot audit program.

The OCR HIPAA Audit program analyzed processes, controls and policies of randomly selected covered entities pursuant to the HITECH Act audit mandate. The entire audit protocol was organized around modules, representing the separate elements of patient privacy, data security and the issuing of breach notifications. The combination of these multiple requirements was then tailored to the type of covered entity selected for audit.

The audit protocol covers Privacy Rule requirements for (1) Notice of Privacy Practices relating to PHI, (2) Rights to request privacy protection for PHI, (3) Individuals’ access to their PHI, (4) Administrative requirements, (5) Uses and disclosures of PHI, (6) Amendment of PHI, and (7) Accounting of disclosures.

The protocol covered Security Rule requirements for administrative, physical, and technical safeguards, Breach Notification Rule requirements and patient access to their healthcare data. The protocol is available for public review, although since the pilot audit program its audit protocol has been amended. Details are available on the HHS website.

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HIPPA Pilot Audit Findings

OCR discovers numerous compliance issues

Two thirds of audited entities had not conducted a full and accurate risk analysis.

980 compliance issues were discovered

Only 13 entities passed without any negative findings

Healthcare providers had 65%of the problems but represented only 53% of the audit set

One third of violations were due to ignorance of HIPAA requirements

58 out of 59 providers had at least one security finding or observation

Data security accounted for 60% of findings and observations, but just 28% of the possible total.

Privacy Rule observations accounted for 30% of findings, while 10% were due to breach notifications

Small HIPAA-covered entities had problems with all aspects of HIPAA

WOULD YOU PASS A HIPAA COMPLIANCE AUDIT?

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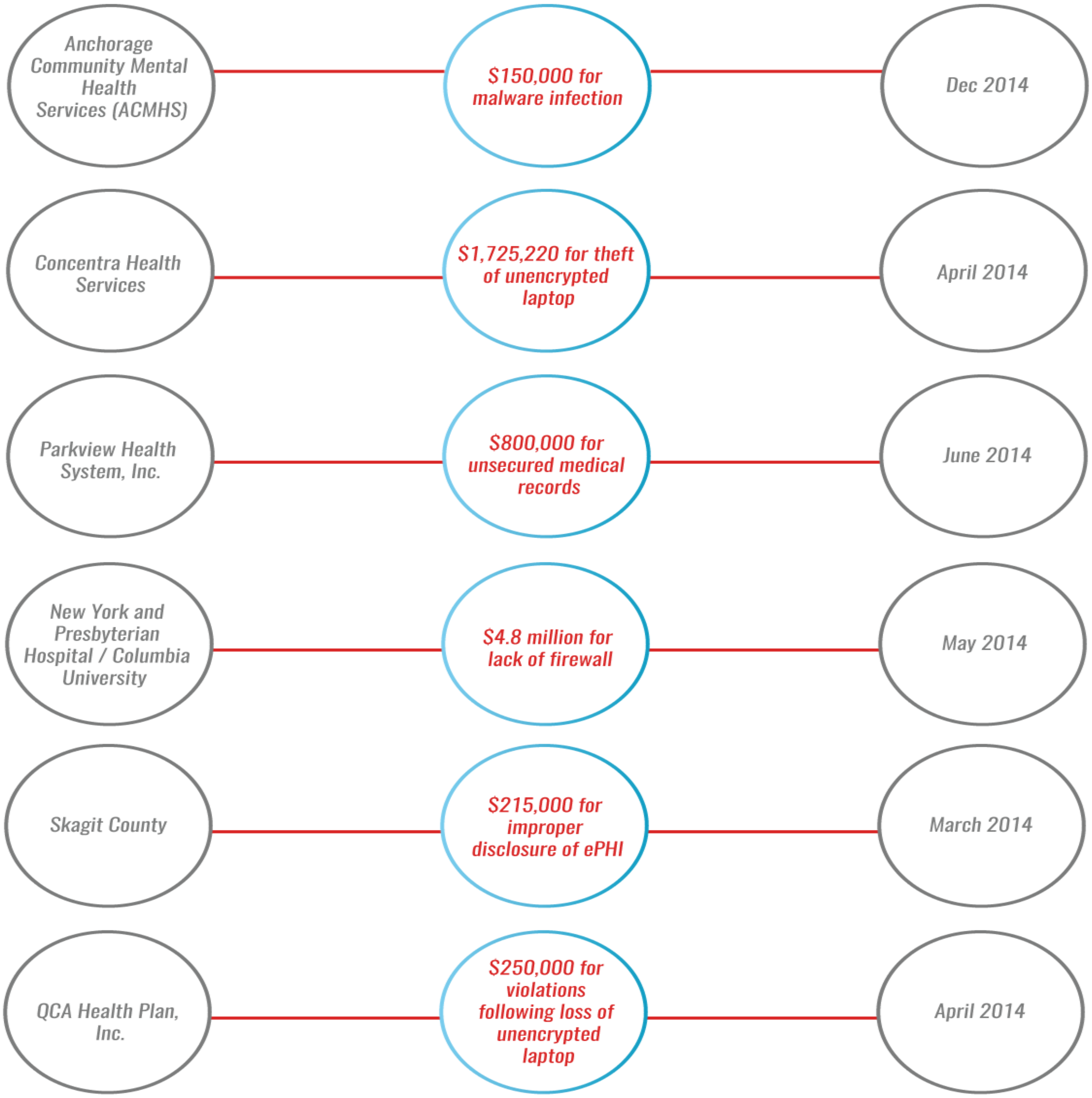
Enforcement Has Already Begun

The Department of Health and Human Services tasked the OCR with policing HIPAA from December 28, 2000 - the date of the issuing of the Privacy Rule. The compliance deadline was April 14 2003, although it took five years before the OCR issued its first fine for non-compliance in 2008. Up until that point over 33,000 HIPAA complaints were filed with the OCR, of which 8,000 were investigated, but it had yet to issue any financial penalties.

OCR Fines for 2014 HIPAA Breaches

Last year the OCR issued a record number of fines for HIPAA violations which resulted in the disclosure of patient data.



Anchorage Community Mental Health Services (ACMHS)	$150,000 for malware infection	Dec 2014
Concentra Health Services	$1,725,220 for theft of unencrypted laptop	April 2014
Parkview Health System, Inc.	$800,000 for unsecured medical records	June 2014
New York and Presbyterian Hospital / Columbia University	$4.8 million for lack of firewall	May 2014
Skagit County	$215,000 for improper disclosure of ePHI	March 2014
QCA Health Plan, Inc.	$250,000 for violations following loss of unencrypted laptop	April 2014

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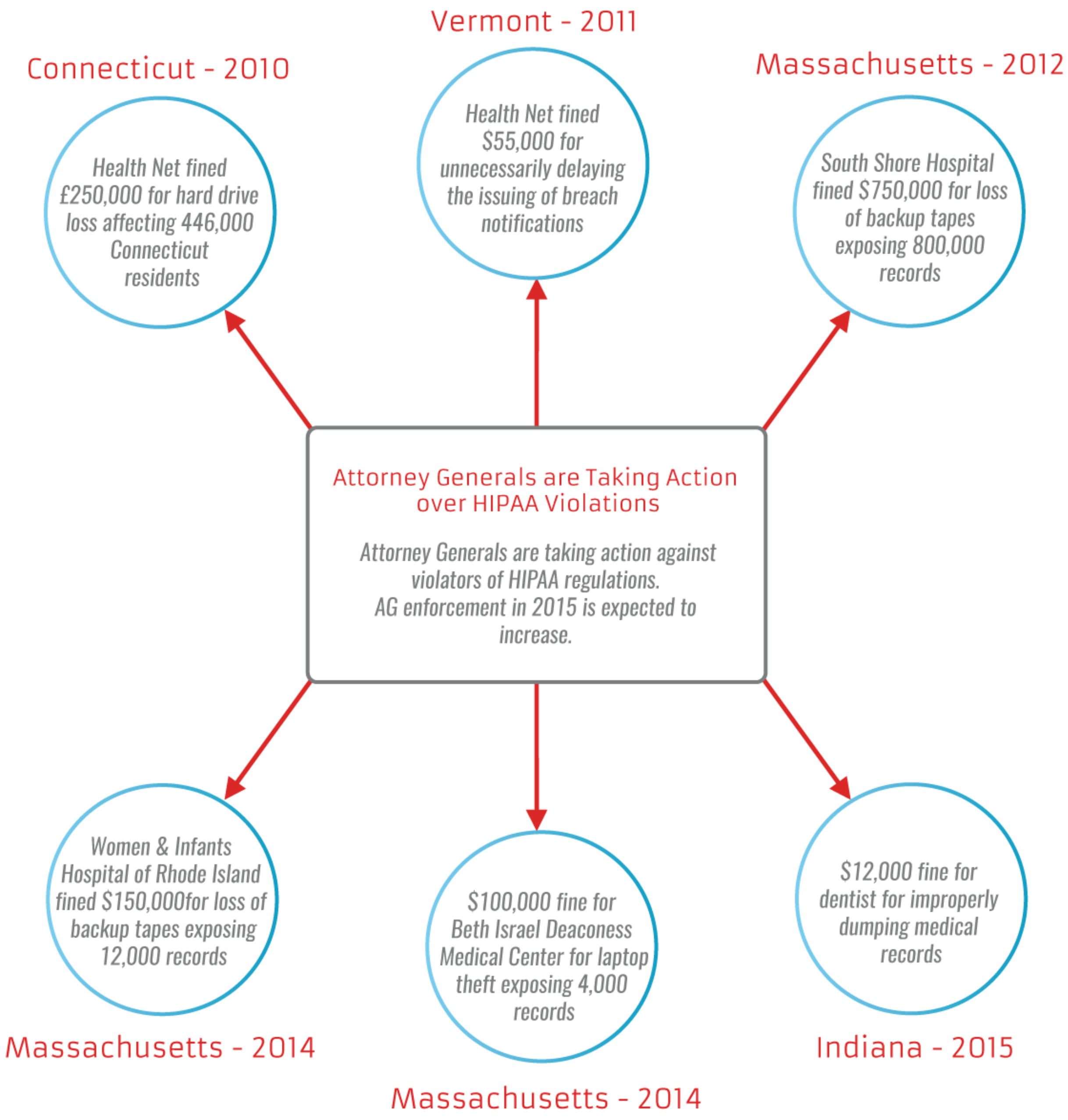
Attorney Generals are Taking Action over HIPAA Violations

Attorney Generals are taking action against violators of HIPAA regulations.
AG enforcement in 2015 is expected to increase.



Attorney Generals are Taking Action over HIPAA Violations

Attorney Generals are taking action against violators of HIPAA regulations.
AG enforcement in 2015 is expected to increase.

Connecticut - 2010

Health Net fined £250,000 for hard drive loss affecting 446,000 Connecticut residents

Vermont - 2011

Health Net fined $55,000 for unnecessarily delaying the issuing of breach notifications

Massachusetts - 2012

South Shore Hospital fined $750,000 for loss of backup tapes exposing 800,000 records

Massachusetts - 2014

Women & Infants Hospital of Rhode Island fined $150,000for loss of backup tapes exposing 12,000 records

Massachusetts - 2014

$100,000 fine for Beth Israel Deaconess Medical Center for laptop theft exposing 4,000 records

Indiana - 2015

$12,000 fine for dentist for improperly dumping medical records

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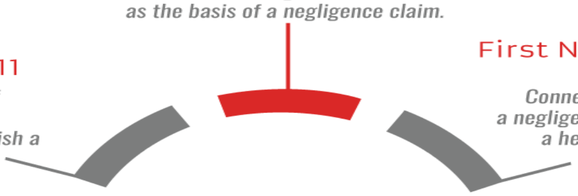
Breach Victims Seek Damages

A failure to implement the necessary safeguards to protect patient and plan member data constitutes negligence. The courts are now allowing negligence claims to be filed by breach victims.



West Virginia - Nov 2014

Court finds that HIPAA does not pre-empt state laws, and the legislation can be used as the basis of a negligence claim.

Missouri - Nov 2011

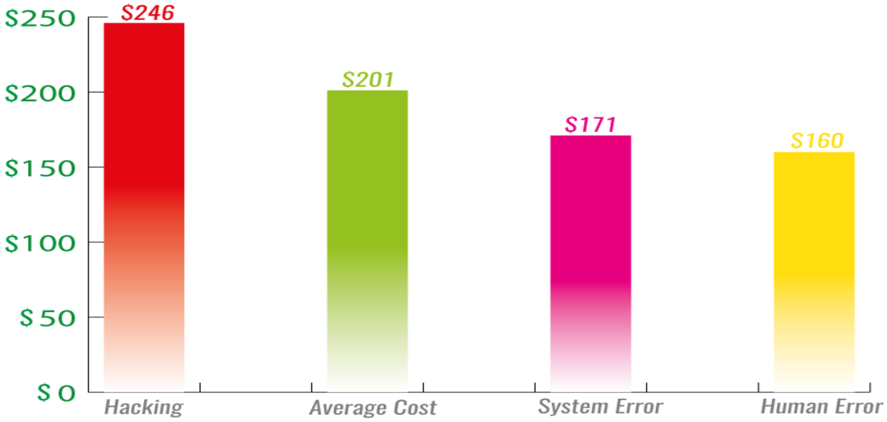
No individual private right of action under HIPAA, but in Missouri HIPAA can establish a legal duty of care.

First Negligence Claim - Nov 2014

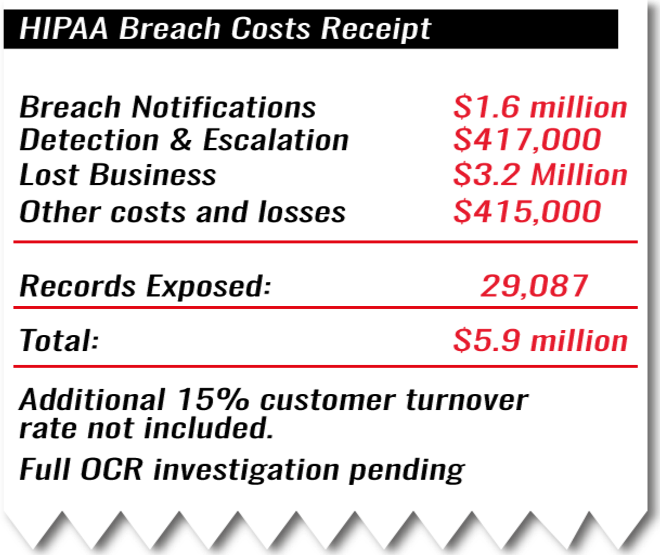
Connecticut Supreme Court allows a negligence claim to be brought against a healthcare provider following a data breach.

The True Cost of Data Breaches

The cost of a HIPAA data breach is substantially higher than the fines issued for non-compliance.



Average HIPAA Breach Costs



HIPAA Breach Costs Receipt

Breach Notifications	$1.6 million
Detection & Escalation	$417,000
Lost Business	$3.2 Million
Other costs and losses	$415,000
Records Exposed:	29,087
Total:	$5.9 million

Additional 15% customer turnover rate not included.

Full OCR investigation pending

The first OCR settlement was reached with Providence Health Services for $100,000 after the loss of backup tapes containing PHI potentially exposed the health information of 386,000 patients. In 2009 further fines were issued, including a $2.25 million fine for CVS Pharmacy Inc., for the improper disposal of patient health records.

In 2010, fines were issued to the Rite Aid Corporation for $1 million, again for improper disposal of health records, a $35,000 fine issued to Management Services Organization Washington Inc. for improper disclosure and in 2011, the OCR issued the first fine for violations of the HIPAA Privacy Rule; a $4.3 million penalty to Cignet Health (Prince Georges County, MD), in this case for denying patients access to their health records.

Since then fines have increased along with the frequency at which they are issued, with a number of 6-figure settlements reached with violators of HIPAA Rules. Even government departments were not exempt. In July 2011, the loss of a storage device by the Alaska Department of Health and Human Services (DHHS) earned a financial penalty of $1.7 million.

In March 2012, the OCR reached a settlement with Blue Cross Blue Shield of Tennessee (BCBST) - the first self reported breach to attract a financial penalty.

In 2014, the OCR issued its largest ever fine, resulting in a settlement with New York Presbyterian Hospital and Columbia University for $4.8 million, due to the lack of a functioning firewall that resulted in a breach that exposed over 1 million patient health records.

It may have taken a long time for the first fines to be issued, but now they are coming thick and fast and HIPAA is being policed much more rigorously. Attorney Generals are also permitted to assist the OCR with policing HIPAA, and a number have now started issuing fines for non-compliance issues at a state level. The days of lax enforcement of HIPAA Privacy and Security Rules have certainly long since passed.

Second Round of HIPAA Compliance Audits

The second round of HIPAA compliance audits was penciled for late 2014, although they have since been rescheduled for 2015. The pilot audits allowed the OCR to gauge HIPAA compliance in healthcare and did not result in fines being issued, but this is not expected to be the case with the second round of compliance audits.

The criteria for the second round differ from the broad nature of the pilot compliance audits. The OCR took the information gained from its first round of 115 audits and developed an audit protocol which specifically tested those areas of HIPAA Privacy, Security and Breach Notification Rules which proved problematic for healthcare organizations, health plans and healthcare clearing houses. The second round of audits will therefore be much narrower in focus and will involve many more compliance audits.

The OCR has announced it will be conducting 400 compliance audits in the second round, involving 350 covered entities and 50 of their Business Associates.

The audits will be highly targeted, with 100 covered entities selected for a Privacy Rule audit, a further 100 for a Breach Notification Rule audit and 150 for a Security Rule audit. The audits will be a mixture of desk-based documentation reviews and compliance audits including a site visit and inspection.

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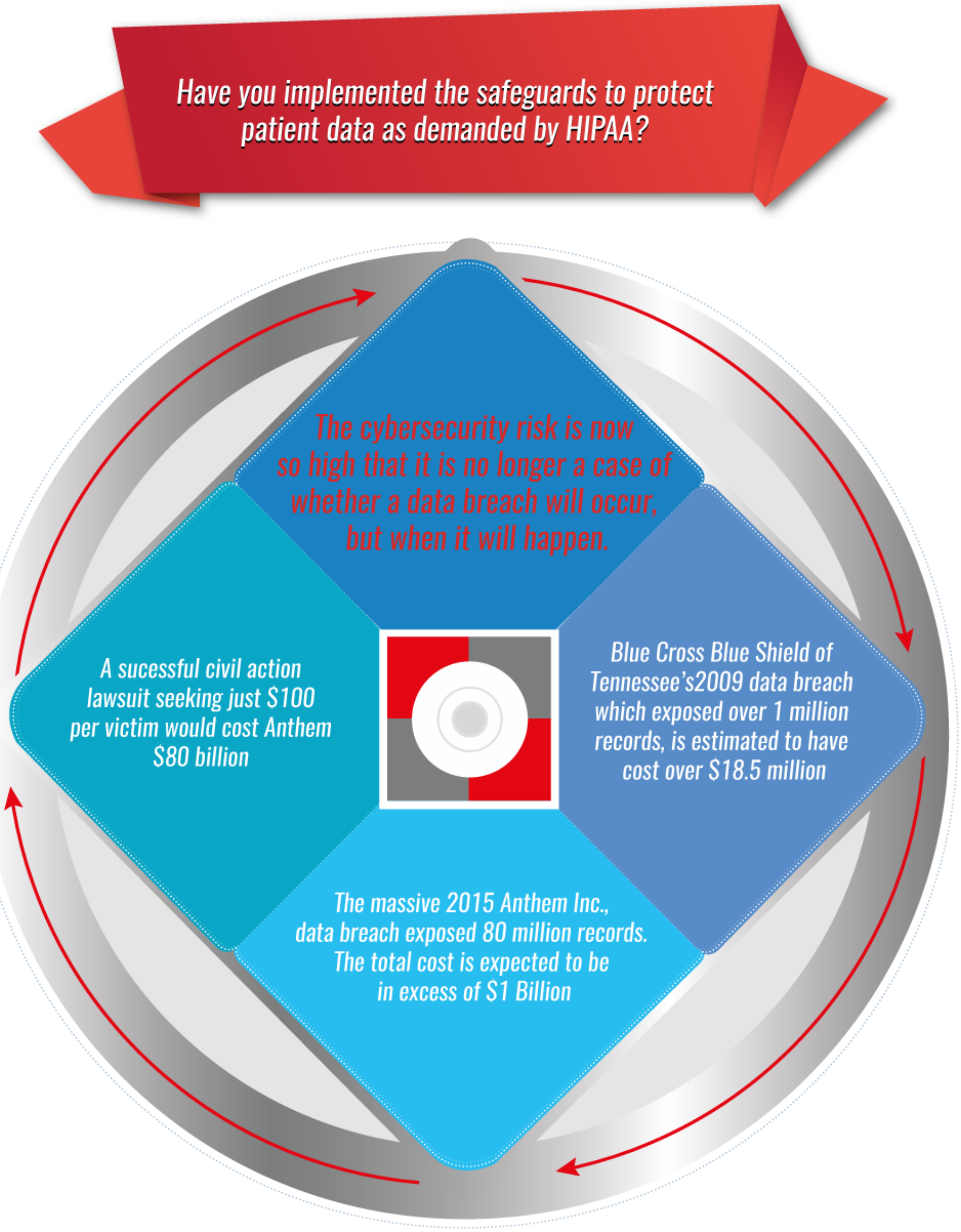
The Cost of HIPAA Non-Compliance

It has been almost two decades since the Health Insurance Portability and Accountability Act was passed in 1996, although it took until 2008 for the first fine for non-compliance to be issued.

Today, the Office for Civil Rights is taking a tougher stance on HIPAA violations,
Attorney Generals are issuing stiff penalties and the victims of data breaches are taking legal action to recover damages.

If your organization has not implemented the appropriate safeguards to protect the health information of patients and plan members, now is the time to take action. Non-compliance carries a significant cost.



Have you implemented the safeguards to protect patient data as demanded by HIPAA?

The cybersecurity risk is now so high that it is no longer a case of whether a data breach will occur, but when it will happen.

A sucessful civil action lawsuit seeking just $100 per victim would cost Anthem $80 billion

Blue Cross Blue Shield of Tennessee’s2009 data breach which exposed over 1 million records, is estimated to have cost over $18.5 million

The massive 2015 Anthem Inc., data breach exposed 80 million records. The total cost is expected to be in excess of $1 Billion

7. Secure Communications and HIPAA-Compliance

How to Make IT Systems and Electronic Communications HIPAA-Compliant

At the heart of HIPAA is the requirement to protect ePHI and to keep all healthcare data private and confidential. While the Health Insurance and Portability Act makes numerous recommendations it is up to the individual covered entity to decide how that data is protected.

All IT systems, devices and software that are capable of touching ePHI must be subject to a full risk analysis to ensure that no security vulnerabilities exist which could expose the Protected Health Information of patients and health plan members.

Our HIPAA Compliance Guide will help you to achieve this and make your computer systems, websites and portable devices secure and compliant with HIPAA Privacy and Security Rules.

Website Security

Doctors and other medical professionals now face increasing pressure to get their business online, make use of electronic prescriptions, web appointments and provide virtual consultations and deliver remote healthcare services. Electronic transactions, websites and patient portals improve the patient experience and are critical for building and sustaining revenue streams in the tightening medical market.

HIPAA Rules require covered entities to ensure that ePHI is protected and secured at all times. All websites, old and new, must therefore be properly designed to ensure that data is secured or site owners face potential financial liability that could run into millions of dollars.

So, how can HIPAA Rules be followed in an online environment and how does the legislation apply to websites and online patient portals?

What are the HIPAA Requirements for a Website?

HIPAA is an unusual law in that it makes a lot of recommendations - addressable items - and a few assertions - required items - but in the end it is up to each organization to determine for themselves what they need to do to become compliant. This allows a great deal of flexibility and also creates a great deal of uncertainty. In general, to be HIPAA-compliant, a website must, at a **minimum,** ensure that all Protected Health Information (ePHI) is safeguarded:

1. **Transport Encryption**: Data must be encrypted if it is transmitted over the Internet
2. **Backup**: Data cannot be lost, I.e. it should be backed up and must be recoverable
3. **Authorization**: Data can only be accessible by authorized personnel using unique, audited access controls
4. **Integrity**: Data cannot be tampered with or altered

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5. **Storage Encryption**: Data should be encrypted when it is stored or archived
6. **Disposal**: Data must be permanently erased when it is no longer needed
7. **Sharing**: If data is located on the web servers of a third party, that entity must agree to comply with HIPAA regulations and a HIPAA Business Associate Agreement must be in place

How Does a Simple Website Stack up Against These Requirements?

By a simple website, we refer to one set with any of the popular hosting providers (e.g. GoDaddy) and written using off the shelf software or by someone without training in HIPAA website security best practices:

1. **Transport Encryption** – **Fail** – Data is not encrypted during transmission
2. **Backups** – **Uncertain** – Most web hosting providers will backup and restore data for you. However, this assumes that the data collected is in a location backed up by the hosting company and those backups are not accessible by unauthorized personnel
3. **Authorization** – **Uncertain** – Depends on how the website set up
4. **Integrity** – **Fail** – No way to be sure that data is not tampered with or to tell if it has been
5. **Storage Encryption** – **Fail** – Data is never encrypted
6. **Disposal** – **Uncertain** – Depends on your website setup; however, some web hosts and IT departments keep data backups indefinitely and they never securely erase data.
7. **Business Associates** – **Fail** – Most web hosting providers do not know what a HIPAA BAA would require them to do. The majority who are aware of HIPAA requirements would not be able to sign such an agreement and comply with HIPAA Privacy and Security Rules without completely changing their business model - and their pricing structure

What Can be Done to Guarantee Compliance?

If you have a simple corporate or informational website that has not been created from the outset with HIPAA in mind, you can be 100% sure that adding any functions that allow ePHI to be accessed, entered into web forms or stored is likely to result in a violation of HIPAA regulations.

Obviously, there are a large number of steps that can - and should - be taken to add the necessary security controls to ensure a website does not cause a HIPAA violation. What will work best for your organization will depend upon exactly what you are trying to accomplish with your site and in what way Protected Health Information is presented, stored and transmitted.

Below, we discuss the seven most common problems that are encountered.

1. **Transmission Encryption***:*

   PHI must be encrypted during transmission

   The first step to secure a website is to make sure it has a SSL Certificate (i.e. the site is accessed via https://). Any page or web form that collects or displays Protected Health Information, or which is used for logging in users, which transmits authorization cookies, etc., must be protected by a SSL

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certificate and must not be accessible insecurely (i.e. there should *not* be an alternate insecure version of the same page that visitors can access).

The use of SSL can meet the HIPAA data transmission security requirement in terms of communications between the end user and your website; however it is essential that the SSL configuration is robust enough and can be trusted. This requires a digital signature by a trusted Certificate Authority or CA.

Browsers include a pre-installed list of trusted CAs, known as the Trusted Root CA store. In order to be added to the Trusted Root CA store, and thus become a Certificate Authority, a company must comply with, and be audited against, security and authentication standards established by the browsers.

An SSL Certificate issued by a CA to your organization's domain/website will verify that a trusted third party has authenticated your identity. Since the browser trusts the CA, the browser will therefore trust your company website as well. The browser will also let patients and other visitors to the site know that it is secure, and your site can be browsed safely and any data entered will be secured.

Next, what if the end user submits PHI that is collected on your website and then your website transmits that data elsewhere or stores it? These processes must also be HIPAA-compliant. We cover these in more detail below, but this will be one of your biggest challenges as it is difficult to ensure HIPAA compliance in this regard.

2. **Backup***:*

PHI cannot be lost - Data needs to be backed up and it must be recoverable

You must be sure that all PHI stored by your website - or collected through it - is backed up and that it can be recovered in case of an emergency or if it is accidentally deleted. Most web hosts provide this service for information stored on their servers. If your site sends information elsewhere - via email for example - then those messages must be backed up or archived and you must take care to ensure that those backups are robust, available and accessible only by authorized people.

Note that the PHI stored in backups must also be protected in a HIPAA-compliant way — with security, authorization controls, data encryption etc.

3. **Authorization***:*

PHI must only be accessible by authorized personnel using unique, audited access controls

Who can access the Protected Health Information that resides on your website or is collected through it? Your web hosting provider almost certainly can. Are they a trusted HIPAA Business Associate and have you obtained an up to date Business Associate Agreement- I.e. one that has been issued or at least revised since the introduction of the Omnibus Rule?

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If your site collects health information - such as allowing appointments to be made - and this information is sent to you or others individuals, it is important to know exactly who can access that information. This cannot be anyone with access to your email or with administrator rights to the website. Are those people trusted, have they received full training on HIPAA Privacy and Security Rules?

If your website stores or provides access to PHI, does it require a unique, secure login that allows only authorized personnel to access that data? Are these logins and the data accesses audited? Does the website alert the Security Officer to multiple failed login attempts? This will be up to your website designers to set up properly for you, and their work must be thoroughly tested and checked to ensure the specified controls exist and are sufficiently robust.

4. **Integrity***:*

   PHI cannot be tampered with or altered.

   Unless the information that you collect and store via your website is encrypted and/or digitally signed, there is no way to prevent it from being tampered with or to verify if tampering has occurred. It is up to your organization to determine if tamper-proofing your data is required and how to best accomplish that. Generally, using PGP, SSL or AES encryption for stored data can accomplish this very nicely and also address the next point.

5. **Storage Encryption***:*

   PHI must be encrypted if it is stored or archived.

   It is up to your organization to determine if data encryption is necessary as it is not a HIPAA requirement, instead it is an addressable issue. However, you should ask yourself: If a data breach occurred which exposed the PHI of patients, would you be able to justify to OCR inspectors your decision not to encrypt data?

   If you decide to use data encryption - and it is strongly advisable to do so - you must ensure that ALL collected and stored Protected Health Information is encrypted and that it can only be accessed/decrypted by individuals with the appropriate security keys. Use data encryption and your backups will be secure and all data will be properly protected (unless your security keys are stolen or divulged).

   Storage encryption is especially important in any scenario where the data may be backed up or placed in locations out of your control, or in cases where a dedicated web server is not used - i.e. it is shared with other customers of the same web host. Should something unfortunate happen and a server become compromised, your liability will be *significantly limited*. It is, after all, not possible for PHI to be viewed without the security key, and even a hacked server will not result in a HIPAA violation if that key is not divulged.

6. **Disposal***.*

   All PHI must be permanently erased when it is no longer required

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This sounds easy. You can just delete the data when it is no longer needed. Unfortunately, deleted data can be recovered and data is frequently stored in multiple locations. It could be located in a backup, on multiple servers or in numerous files and folders.

You must consider *all* of the places where the data could be backed up and archived. You need to ensure that all of those backups are either scheduled for deletion after a finite period of time and when that occurs, they are securely and permanently erased.

Consider that any software that touches PHI could be making backups and saving copies of your data for an indefinite period of time. It certainly helps if the data is encrypted in the backup, but if the backup is there and the keys to open that data exist, it is not really "disposed of".

It is up to you to determine how far you need to go to ensure ePHI is disposed of securely.

7. **Business Associates***:*

You must have a signed HIPAA Business Associate Agreement with every vendor that touches your PHI

If your website or data is located on the servers of a vendor, then HIPAA (first in HITECH and subsequently in the Omnibus Final Rule) requires you have a signed and up to date Business Associate Agreement with them. This agreement ensures that the vendor is aware of HIPAA Privacy and Security Rules and agrees to follow them at all times.

Note that websites are complex beasts and no web hosting provider will be policing your website functionality and its content. They will only provide an environment that meets HIPAA requirements. It is up to you to ensure that your site is designed and managed in a way that is compliant with HIPAA.

Choosing a HIPAA-compliant provider will not make your website HIPAA compliant unless you and your designers ALSO take all of the steps to ensure that its design and functionality is complaint. This is universal *unless* you buy a website that is pre-designed by, and fully under the control of, a HIPAA-compliant host.

So, there are many things to do and a lot is all up to you. Of course, just because you have control over the measures you implement - or don't implement - it doesn't mean that you can make whatever choice you feel like. If you make a poor choice and a data breach occurs - or if you are audited - you are likely to be found to be willfully negligent.

Depending on the nature and extent of the breach - or severity of the HIPAA violation - this could potentially result in a fine of up to $1.5 million, per violation category, per year that the breach or violation has been allowed to exist. While your insurance policy may cover the cost of a breach, bear in mind criminal charges may also be filed in cases of willful negligence.

You therefore must carefully consider what is necessary and appropriate to suitably protect health information and the privacy of your users, and these decisions should be based on your website applications and how patient healthcare data and personal identifiers are used and transmitted.

Collecting Health Information from Website Visitors

One of the first things that doctors and medical practices like to do when they expand online is to collect patient information on their website to enable them to:

- Sign up new patients
- Schedule appointments
- Make diagnoses and recommendations about medical conditions
- Start issuing digital prescriptions

Securing the transmission of information from the patient to the website is pretty easy (it's point #1 — use website secured with a SSL Certificate). However, what do you **do** with the information collected via your website?

1. Do you store it in files on the web server to download later?
2. Store it in a database for download or remote access?
3. Email it to someone?

The third option, having the data emailed to someone, is the most popular choice because it is the *easiest* and requires the least additional software or infrastructure. However, it does pose a number of problems as email can be intercepted and can potentially be accessed by unauthorized individuals. So how do you make the email component meet the minimum HIPAA Privacy and Security standards and ensure that data stored or downloaded is properly protected?

1. Storing PHI in files requires:

- The website to automatically encrypt the files
- Downloading the files is only possible via a secure channel (i.e. Secure FTP)
- The website owner receives a notification via an email that a new file is waiting
- Backup and secure disposal of PHI is taken care of

2. Storing PHI in a database

This allows you to write software for remote access and management of that information, however…

- Transmission to and from the database needs to be secure
- The software that provides management access must be secure and meet many HIPAA requirements governing access control and auditing
- Issues regarding encryption keys and database secure storage must be addressed

So, option 1 is easy, but requires some technical knowledge on the part of the users and puts the onus of backup and disposal on them. Option 2 is better and allows more flexibility, usability and control and a centralization of all data. However, Option 2 is more technically complex and requires a significant cost - and effort - to implement properly. Option 3 is easy, but how do you make the email component HIPAA compliant?

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3. Securing Data Emailed from your Website Forms

The ideal procedure for securing your emailed data is as follows:

- Your secure website encrypts the submitted data (using PGP or S/MIME, TLS or another secure web-based email pickup solution) such that only a limited number of authorized individuals can open the files and view the data they contain
- The data is emailed to those recipients and erased from the website (or an encrypted copy is stored on the site if you prefer)
- The recipients receive the data and it is stored on their email server (still encrypted unless TLS was used for delivery)
- The recipients can access these messages securely (over SSL) and decrypt the data either in their email program or via a web-based interface that supports decryption.
- The email provider takes care of backups
- Deleted messages will expire from backups after a finite period of time. (Obtain a signed statement from your vendor confirming this)
- Keep copies of all of the encrypted messages on the server instead of downloading them all, so that you are responsible for backups and make sure they are all stored in a central location.

Quickly Make your Web Forms HIPAA-Compliant

There are a number of HIPAA-compliant providers who can help you achieve this. For example, LuxSci's SecureForm service allows you to collect data from your web (and PDF) forms and delivers it to you via email, secure FTP or populates your database in a way that is both automatically HIPAA-compliant and does not require any programming on your part. SecureForm service also ensures:

- A SSL Certificate exists for your website so that data entered is secured
- Integration of your web forms with special scripts that encrypt your submitted form data (using PGP, S/MIME, TLS, or SecureLine Escrow) and email it to you.
- You are provided with daily and weekly backups of your email data that permanently expire after 1 month
- An option of immutable archives of all of your inbound and outbound email so that it is impossible to lose data and allows secure backups to be stored for 1, 3, 5 or 7 years, depending on your needs.
- The provision of web browser-based email access that allows you to decrypt and view all of your secure messages, over a secure channel, from any location
- Compatibility with your favorite email clients (Thunderbird, Outlook, Eudora etc.) to securely access, unlock and read the secure email messages over IMAP (or POP) or from your iPhone, Android Smartphone, tablet, laptop of desktop computer
- Secure communications that enable users to reply, via a WebMail interface or even from an email program, back to the website user in a secure and HIPAA-compliant fashion. Website users can also reply to the medical worker securely
- HIPAA-compliant back-and forth conversations, initiated from your website

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Internal IT Network Security

Network security is a vital element of HIPAA. You must ensure your facility has robust multi-layered information security protection that safeguards ePHI and keeps it secure at all times. Measures must be introduced that protect against intrusion, offer extended connectivity, allow easy incorporation of software packages and bespoke programs and permit secure backups of data while eliminating downtime.

There are a number of companies that offer HIPAA-compliant networks for healthcare providers, health plans, clearinghouses and other covered entities, such as the Medical-grade networks offered by Cisco and SonicWALL healthcare information solutions from Dell. These scalable solutions provide the framework that allows HIPAA-compliant interactions between healthcare professionals, processes, applications and software and hardware components.

While these network solutions can be invaluable for healthcare providers looking to comply with HIPAA regulations and the Meaningful Use Incentive program, they are not a universal solution that will guarantee compliance with Privacy and Security Rules. There are many potential areas for HIPAA violations to occur, with the following devices posing a particularly high risk of ePHI exposure as they can be accessed from outside of the healthcare environment. As such, they are the most likely source of intrusion and are all potential areas that hackers can use to gain access to healthcare databases.

- Routers
- Firewalls
- Virtual Private Networks (VPNs)
- Wireless Access
- Windows-Based Email and Web Servers

Each of these devices must be thoroughly checked by conducting a comprehensive risk analysis, and each item must be certified as being secure and compliant with HIPAA regulations. HIPAA requires organizations to implement a multi-layered security system and the first layer is usually the router, not the firewall. A router helps to protect a firewall from attack, not the other way round.

Routers

While a Firewall will protect a network against intrusion, a router can offer some protection for the firewall and ease the burden placed on it to stop unauthorized access to internal healthcare systems. Routers are not specifically mentioned in HIPAA, but that does not mean they are not a major risk.

A router filters unwanted external traffic and acts as a packet filter which stops the Firewall from having to analyze each packet presented to the router; however, routers must be configured for the healthcare environment where they are used.

Each router is supplied with a set of security controls by the manufacturer, and in a home environment, this may be sufficient, but in a healthcare environment, where targeted attacks are likely, they do not offer the required level of protection.

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An Access Control List (ACL) should be used. This allows security filtering and blocks to be placed on IP addresses, while extended ACLs also deny or permit packets based on packet header information, protocols or port numbers.

The golden rule for securing routers is to configure them to deny all packets unless they are specifically designated to be allowed, rather than to allow all packets unless they are specifically denied. It is also a good best practice to close any ports which are not in use.

Routers must also be thoroughly tested, and penetration software such as Nmap, Netcat, Nessus and Enum can be used to achieve this and determine whether the router has been configured correctly. It is also essential that routers are monitored for intrusion attempts, and must be configured to automatically generate audit logs - which must be checked frequently for signs that access has been attempted or allowed.

It is all too easy to concentrate on the technical aspect of network security, but the routers themselves must be protected from tampering. It is a quick and easy process to reset routers to factory standards and undo protections, so they must also be physically secured and access to the location where they are housed must be controlled.

Firewalls

The second line of defense against unauthorized access to healthcare computer systems is the Firewall. A Firewall offers packet-level security and acts like a router in this regard, denying or allowing access. A Firewall must be placed between the internal servers and the external environment, such as between an internal server and the connection to the Internet, and also between web and mail servers and the Internet.

There are numerous types of Firewall that can be used as detailed below, with each offering benefits and disadvantages.

Stateful Application Gateway Proxy - Opens up packets, inspects them and rewrites them. These are secure, but slow.

Appliance Firewall - Appliance firewalls are easier to install, although they are more expensive.

Packet Filters - While effective and offering a high degree of protection, they can be complicated to set up and next to useless if not configured correctly.

Application Proxies - These are secure, offer a high degree of protection and are flexible, although they use considerable system resources and have a tendency to be slow.

Stateful Inspection Firewalls - Correct configuration is essential, but these firewalls are faster and offer a compromise between a secure application proxy and the less secure packet filtering.

Software Firewalls - Offer an increased level of protection, although they are insufficient protection on their own and should never be used without a network firewall.

As with routers, Firewalls should block all access to the external environment and prevent access to internal systems unless they are specifically allowed and their configurations must be tested, there must be automatic reporting of failed and granted access and procedures should be developed to ensure that the firewall is always active.

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Virtual Private Networks (VPNs)

A Virtual Private Network or VPN can be used to allow users to access internal systems through a secure tunnel through public networks, such as accessing internal systems via the Internet, and incorporate encryption of data transferred through them and a system to authenticate users.

Different levels of security exist, and while not perfect, the IPSec protocol offers an appropriate degree of protection provided that the VPN has been correctly configured at both ends: The user end and the internal servers which are accessed via the VPN.

A VPN offers some protection, but alone this is insufficient and other security measures must also be used. One important point is that users must not be connected to the internal network via the VPN at the same time as being connected to the Internet unless a personal Firewall is installed on the device and is active. Audit logs should also be automatically generated to ensure intrusion attempts can be identified.

Wireless Access

Wireless networks allow medical professionals to connect to internal networks via hand-held devices, allowing them instant access to ePHI such as medical records and test results. Since no cables are needed, a wireless network allows data to be accessed from any area of the facility, such as treatment or examination rooms.

However, wireless network access is inherently insecure. The signals are sent out in all directions, including outside of the facility itself, and offer a way into the internal network. Because of the high risk, healthcare organizations should opt for closed network via the wireless network and should take the following actions:

- The wireless router should be positioned in a location that restricts the distance outside the facility the signal can be sent. I.e., not placing it next to an external wall or window, instead locating it centrally in the building
- Wireless networks should be configured using WEP (Wireless Encryption Protocol). This should not be confused with other more robust data encryption methods used to protect the data itself, as WEP is not completely secure
- Change factory default logins and passwords. Use long alphanumeric passwords to offer a greater level of security
- Use Access lists which control who can connect to the network
- Change the SSID along with the default login details
- Disable DHCP and only use assigned IP addresses on WAPs and on the devices used to connect to them
- Only allow access to wireless networks via a VPN

Windows-Based Web Servers

Windows based web servers are easy to hack, especially if patches and updates are not installed. Security holes do exist, although Microsoft plugs these holes quickly once they are identified. Microsoft does this by issuing updates and patches. Servers must be configured to update and install these automatically.

If a server is not patched it will be particularly vulnerable to attack, and may not only result in the data on the server being exposed, but a hacked server can be used to connect to other servers in the facility.

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A good best practice is to make sure all default configurations are changed, including scripts, the location of the web folder and default system permissions. All default users must be removed from the server as these are one of the main methods used to improperly access servers.

Procedures must be developed governing the creation of passwords. Only strong passwords should be permitted, while users should be required to change these periodically, say, every 6 months.

Posix and OS/2 should be removed and NetBIOS disabled. O/S, HTML and FTP folders should also be separated, using hard drive partitions or even better, separate hard drives for each.

You must also ensure that antivirus software is installed, that it is automatically updated with new definitions and routine scans of the server should be conducted to check for viruses and malware which may have bypassed other security controls.

Email Security

What are the HIPAA Rules for Email Encryption?

The HIPAA email encryption rules do not exclusively apply to emails, but to all communications which contain Protected Health Information that was in electronic form before it was communicated. Therefore attachments to emails, SMS and IMs are governed by HIPAA rules for email encryption, but not faxes or voice-mail messages (unless they are saved in electronic form after they have been received, in which case the Security Rule provision for Protected Health Information at rest applies).

What HIPAA actually says about email encryption is that covered entities must “implement a mechanism to encrypt and decrypt electronic Protected Health Information”, and most communication experts agree that healthcare organizations who want to facilitate the communication of Protected Health Information by email should double their encryption protection, so that encrypted communications are sent over an encrypted connection “just to be on the safe side”.

Why the Communication of Protected Health Information by Email is Insecure

The experts´ wariness about HIPAA email encryption rules is based on several possible scenarios in which a breach of Protected Health Information could occur when the data is communicated by email.

For example:

- When emails are sent using public FTP (File Transfer Protocol), copies of the emails will remain on routing servers indefinitely with no possibility of an organization being able to delete them if a breach of Protected Health Information is identified
- There is no possibility of retracting an email containing Protected Health Information if it has been sent to the wrong person, or to remotely delete emails if an authorized user loses a mobile device from which Protected Health Information has been communicated
- There is also the logistical issue that each authorized user would have to install encryption/decryption software on all the mobile devices and desktop computers they would use for

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the communication of Protected Health Information by email, and that the software would have to operate across all platforms

- Furthermore, any solution that is implemented to comply with HIPAA rules for email encryption would also have to have administrative controls to monitor access to Protective Health Information. You must also ensure that the policies developed to comply with HIPAA email encryption rules are being adhered to

An Alternative to Encrypted Emails

There is an alternative to encrypted emails, and that is to use a secure messaging platform. This works by allowing access to Protected Health Information through a software-as-a-service “On Demand” app. The app can conveniently be used from any desktop computer or mobile device, while administrative controls safeguard the integrity of Protected Health Information.

Access to Protected Health Information is only available to authorized users who are assigned a unique username and PIN, and whose activity on the secure messaging platform is monitored by access reports and audit logs.

As all activity is contained within a private network, should a breach of Protected Health Information be identified, administrators can remotely delete a message - unlike when the communication of Protected Health Information is sent via email - or remotely wipe the user from the system if their personal mobile device is lost or stolen.

Secure messaging apps have been purposefully designed with the end-user in mind; and medical professionals, Business Associates and third party service providers should find the text-like interface familiar and easy to use, making it less likely that they would revert to alternative insecure channels to communicate Protected Health Information.

The Benefits of Secure Messaging Over Secure Emails

Research conducted on mobile device users has shown that messaging is by far the most popular form of mobile communication, with 92% of mobile users preferring it over email because of the speed of delivery. A further fact, revealed in a 2012 survey, was that respondents considered text communications to be more urgent than emails - and required an immediate response, rather than delaying an answer until it was more convenient.

In a healthcare environment, the speed of response can have substantial benefits to patients, plus there are additional benefits for medical professionals and healthcare organizations when secure messaging is used, such as accelerating patient concerns, making faster diagnoses, delivering lab results quickly and efficiently and assisting in the administration of medical treatment.

- Secure messaging apps have a message forwarding feature which enables multiple parties to collaborate securely about the care provided to a patient
- Authorized users receive delivery notifications and read receipts that confirm their messages have been received and which eliminate phone tag
- Secure messages can be assigned a lifespan and delete automatically after a pre-determined period of time

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- A “search by name” facility helps eliminate the risk of messaging errors often seen with encrypted email, and accelerates secure communications between medical professionals

Each of these features helps to streamline workflows, increase productivity and improve the standard of patient healthcare in a cost-effective manner, while maintaining the integrity of Protected Health Information at all times.

Text Messages and Replacing Pagers

Finding a pager replacement for hospitals has become a priority for healthcare organizations since legislation was enacted in the Health Insurance Portability and Accountability Act (HIPAA) to increase patients´ privacy and the security of electronic Protected Healthcare Information (ePHI).

Pagers are inherently insecure channels of communication for transmitting ePHI, as there is no accountability over messages that are sent by pager and no automated auditing option. Pager messages can be missed, sent to the wrong recipient and intercepted by a third party when the pager is left lying around.

Other issues of concern - and why finding a replacement for hospital pagers has become a priority - are the limitations of paging systems. It is not possible to share images on a pager - thus making them impractical for healthcare organizations that want to create a team-based care environment - and, due to the restricted coverage of paging systems, they are inappropriate for medical professionals working in the community.

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What HIPAA has to Say about Communicating ePHI via a Pager

The HIPAA Security Rule introduced administrative, physical and technical safeguards that stipulate how ePHI should be stored and communicated. In order to be compliant with the HIPAA Security Rule, healthcare organizations must be able to identify the sources of all ePHI that is created and monitor how it is maintained, accessed and communicated.

As healthcare organizations have no control over what is communicated via a pager, it is not possible to comply with HIPAA when a paging system is implemented in a hospital environment. So, although HIPAA does not specifically mention anything about communicating ePHI via a pager, healthcare organizations using paging systems have two options if they are to become HIPAA-compliant - either prohibit the communication of ePHI through the paging system or find a pager replacement for hospitals.

Using Existing Technology as a Pager Replacement

The most obvious solution is to use existing technology as a pager replacement. Numerous surveys have shown that up to 80% of healthcare professionals use a Smartphone or other personal mobile device in hospitals, and harnessing this existing channel of communication is a cost-effective way of dealing with the pager issue, provided of course that any messaging conducted between personal mobile devices is HIPAA-compliant.

HIPAA compliance can be assured by using secure texting. Secure texting replicates the speed and convenience of SMS messaging, but has the controls in place to prevent potential breaches of ePHI. Secure texting also has the benefits of limitless coverage and the ability to exchange images and foster a collaborative healthcare environment. It can also be used by healthcare organizations to qualify for Meaningful Use incentive payments.

Secure Texting as a Replacement for Hospital Pagers

Secure texting requires everybody connected to the healthcare organization´s network to download a secure texting app. The app has a text-like interface which will be familiar to any healthcare professional that has a mobile phone, and it enables them to communicate ePHI securely, share information with colleagues and receive notifications that their communications have been received and read - thus overcoming issues such as accountability and recipient delivery and eliminating productivity-reducing phone tag.

The platform through which all secure texts pass has administrative controls that have the ability to remotely retract and delete text messages, assign message lifespans - so that messages are deleted and archived automatically - time out a mobile device if it has been inactive for a period of time, and remove a user from the organization´s network if the mobile device is lost or stolen or their employment is terminated.

In addition to ensuring compliant usage of the secure messaging solution, the administrative controls also produce audit reports to comply with the HIPAA safeguards for monitoring how ePHI is maintained, accessed and communicated.

Secure Texting Solutions in Practice - Case Studies

TigerText is a leading provider of secure texting solutions, and their platform has allowed healthcare pagers - and hospitals in particular - to replace the pager entirely. To date the secure messaging system has been

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implemented in more than 4,000 medical facilities. Case studies show how - acting as a pager replacement - TigerText´s secure texting solution has streamlined workflows, increased productivity and enhanced the standard of patient care. Three examples that are particularly relevant to healthcare organizations looking for a HIPAA-compliant pager replacement are:

- Memorial Hospital of Gulfport - TigerText´s secure messaging solution was used as a replacement for hospital pagers with the result that these outdated forms of communication could finally be retired, and secure messages are now integrated with the hospital´s answering service and EHRs while staff communications have been streamlined. The hospital estimates that the secure messaging solution has saved thousands of dollars.
- San Joaquin General Hospital in California had a different reason for sourcing a pager replacement. Their overhead paging system was inefficient and hindering their HCAHPS score. San Joaquin chose TigerText and benefitted from an accountable message delivery and receipt system, that enhanced clinical workflows, accelerated patient hand-offs and improved their HCAHPS score.
- Concordia Lutheran Ministries in Pennsylvania was a different scenario, where the aim was to implement a priority messaging channel in order that offsite staff members could escalate patient concerns securely and deliver patient care more quickly. With the ability to attach files and images to secure messages, workflows accelerated and offsite staff members were able to spend more time providing medical care to patients.

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8. The Benefit of HIPAA Compliance Tools

Why is HIPAA so Important?

The Health Insurance Portability and Accountability Act was a landmark bill that introduced sweeping changes in the healthcare industry. The bill was originally introduced with two main aims: To allow individuals to maintain their health insurance between jobs and ensure the security and confidentiality of patient information and healthcare data. New standards were also introduced covering the electronic transmission and storage of data relating to patient health information.

The bill limits the pre-existing condition restrictions that a group health insurance arrangement can enforce, meaning that as long as individuals have continuous coverage, a group policy cannot exclude a pre-existing condition.

HIPAA has made a considerable difference to how healthcare data is stored, transmitted and safeguarded. As the healthcare industry has moved from physical records to electronic versions, the risk of that data being exposed or viewed by unauthorized individuals has increased considerably. HIPAA is therefore an essential piece of legislation that forces healthcare providers and other covered entities to implement a wide range of safeguards to protect the privacy of patients and health plan members.

For patients and health plan members the benefits of HIPAA-compliance are clear. Data is protected and insurance coverage secured. A HIPAA-compliant healthcare organization also inspires confidence and trust, and assures the public that the organization in question is committed to protecting the privacy of its patients and plan members.

However, for organizations covered by HIPAA the benefits may not be immediately apparent, and it is all too easy to focus on the disadvantages that come from HIPAA. Becoming compliant involves committing a considerable amount of resources to improving security and protecting privacy, it requires greater investment in software and hardware and it carries a considerable administrative burden and the cost of HIPAA-compliance can be considerable.

Those costs must be found from somewhere and some medical professional argue that that money diverted to compliance would be better spent on improving the healthcare services provided to patients. However, even with the cost, the advantages of HIPAA far outweigh the disadvantages.

The Benefits of HIPAA Compliance

The main benefit of healthcare providers, health plans and healthcare clearinghouses becoming HIPAA-compliant is that it is the only way that these organizations will be able to avoid multi-million dollar fines. Becoming HIPAA-compliant is, after all, not a choice but a requirement.

While enforcement was been lax in the early years of the legislation, since 2009 the Office for Civil Rights, along with State Attorney Generals, have been policing HIPAA more rigorously and major fines are being issued to organizations that have suffered data breaches as a result of a failure to implement the appropriate safeguards to protect data. Fines can also be issued for non-compliance, even in the absence of a data breach.

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There is a considerable cost advantage to becoming HIPAA-compliant, and while it may involve a significant initial cost - and ongoing costs to stay HIPAA-compliant - they pale into insignificance compared to the costs associated with a HIPAA data breach.

It is not only fines from the Office for Civil Rights and state Attorney Generals that covered entities have to cover. The cost of issuing breach notifications and damage mitigation can run into millions of dollars.

The mega data breach that affected Anthem Inc., in February, 2015 exposed 80-million records. The initial estimates of the cost of the breach were well in excess of 100 million. The reality however is likely to be far worse. Some industry experts have predicted that the final cost of the data breach – which will not be known for some time - could well rise to $1 billion. These estimates do not even take into consideration the loss of revenue that may come as a result of consumers losing trust in the insurer’s ability to safeguard their healthcare data.

There are many more benefits to healthcare organizations than cost savings, many of which come from the transition from physical records to EHRs.

The Health Insurance Portability and Accountability Act therefore:

- Helps covered entities prevent data breaches and restricts the damage caused when they do occur
- Ensures that in the event of an emergency, healthcare services can still be provided
- Makes sure healthcare data cannot be lost or accidentally deleted
- Improves efficiency
- Improves access to healthcare information
- Streamlines the provision of medical services
- Allows organizations to qualify for Meaningful Use financial incentives
- Improves patient confidence and trust

When HIPAA was introduced one of the aims was to create a simpler, more standardized healthcare system that would eventually lower health care costs while reducing errors through safe, universally accepted electronic communication of healthcare transactions.

It has now been almost 20 years since the introduction of the legislation and while the jury may still be out on the effectiveness of the bill - and whether HIPAA has been worth the time, energy, and financial investment - consumers have certainly receive many important benefits and, over time, so will the organizations that implement the standards necessary to comply with HIPAA.

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Appendix:

HIPAA Summary	http://www.hipaajournal.com/hipaa-explained/
A Short History of HIPAA	http://www.hipaajournal.com/hipaa-history/
HIPAA Compliance Checklist	http://www.hipaajournal.com/hipaa-compliance-checklist/
Office for Civil Rights	http://www.hhs.gov/ocr/office/index.html
OCR Breach Reporting	https://ocrportal.hhs.gov/ocr/breach/wizard_breach.jsf

HIPAA Security Rule Guidance

HIPAA Security Rule http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/index.html

HIPAA Security Rule Guidance

http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html

Security Risk Assessments

http://www.healthit.gov/providers-professionals/security-risk-assessment

HHS – Final Guidance – Risk Assessments

http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf

Security Standards – Final Rule

http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityrulepdf.pdf

Security and Electronic Signature Standards

http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/srnprm.pdf

HIPAA Privacy Rule Guidance

HIPAA Privacy Rule http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html

Notice of Privacy Practices

http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html

Health Information Privacy Rights

http://www.hhs.gov/ocr/privacy/index.html

De-identification of PHI http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/deidentificationworkshop2010.html

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Breach Notification Rule Guidance

HIPAA Breach Notification Rule http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/index.html

Example Breach Notification Letter http://www.hhs.gov/ocr/privacy/hipaa/enforcement/audit/sample-ocr_notification_ltr.pdf

HIPAA Enforcement Rule Guidance

HIPAA Enforcement

http://www.hhs.gov/ocr/privacy/hipaa/enforcement/index.html

HIPAA Resolution Agreements http://www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/index.html

HIPAA Enforcement – State Attorney Generals http://www.hhs.gov/ocr/privacy/hipaa/enforcement/sag/index.html

HIPAA Omnibus Rule Guidance

HIPAA Omnibus Rule

http://www.hhs.gov/news/press/2013pres/01/20130117b.html

HITECH Guidance

HIPAA and the HITECH Act

http://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf

Business Associate Guidance

Business Associate Contracts

http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html

Business Associate Guidance

http://www.hhs.gov/ocr/privacy/hipaa/faq/business_associates/

HIPAA Compliance Audit Guidance

HIPAA Compliance Audits http://www.hhs.gov/ocr/privacy/hipaa/enforcement/audit/index.html

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Additional Information and References

HIPAA, FERPA and Student Health Records

http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/hipaaferpajointguide.pdf

HIPAA and Digital Copiers

https://www.ftc.gov/tips-advice/business-center/guidance/copier-data-security-guide-businesses

HIPAA and Secure Text Messaging

http://www.hipaajournal.com/does-your-organization-need-a-secure-text-messaging-service-324/

HIPAA in Emergency Situations
http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/emergencysituations.pdf

HIPAA and Workplace Wellness Programs

http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/wellness/index.html

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